U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5101-5140

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 14, 1958.*

CONTENTS

VIOLATIVE SALES OF PRESCRIPTION DRUGS

5101. (F. D. C. No. 39333. S. Nos. 34–834/7 M.)

INDICTMENT RETURNED: On or about 12–4–56, S. Dist. Ind., against **Wayne Reel, t/a Dixie Cabins, Vincennes, Ind., and Jack Stilwell (employee).**

CHARGE: Between 2–24–56 and 2–29–56, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2–14–57. Fine of $250 against Reel and $100 against Stilwell. Each defendant also given jail sentence of 6 months, which was suspended, and placed on probation for 6 months.

5102. (F. D. C. No. 39196. S. No. 34–829 M.)

INFORMATION FILED: 7–18–56, S. Dist. Ohio, against **Nathan Drucker, t/a Drucker Hy-Pure Drugs, Cincinnati, Ohio.**

CHARGE: On 1–25–56, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–30–56. Fine of $350.

5103. (F. D. C. No. 39195. S. No. 34–827 M.)

INFORMATION FILED: 7–18–56, S. Dist. Ohio, against **Walter J. Fallon, t/a Fallon's Pharmacy, Cincinnati, Ohio, and Norman H. Grevious (pharmacist).**

CHARGE: On 1–25–56, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–30–56. Fine of $350 against Fallon and $150 against Grevious.

5104. (F. D. C. No. 39359. S. Nos. 28–108 M, 39–099 M.)

INFORMATION FILED: 12–26–56, M. Dist. N. C., against **Otho Morgan, t/a M & M Truck Stop, New London, N. C.**

CHARGE: On 5–24–56, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4–15–57. Fine of $500 and defendant placed on probation for 2 years.

5105. (F. D. C. No. 38609. S. Nos. 23–131 M, 23–140 M, 23–606 M.)

INFORMATION FILED: 6–6–56, Dist. Mass., against **Herman H. Seligman, t/a Roma Pharmacy, Boston, Mass.**

CHARGE: Between 11–8–55 and 12–1–55, *amphetamine sulfate tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–14–56. Fine of $500, prison sentence of 6 months suspended, and defendant placed on probation for 1 year.

5106. (F. D. C. No. 39325. S. Nos. 38–338 M, 38–341 M, 43–036 M.)

INFORMATION FILED: 8–3–56, E. Dist. Mo., against **Cornelius L. Mueller (manager and pharmacist of Mueller Drug Store), St. Louis, Mo., John J. Mueller, Jr. (employee), and Maurice Gengler (pharmacist).**

CHARGE: Between 12–23–55 and 2–1–56, *dextro-amphetamine sulfate capsules, thyroid strong tablets, and pentobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty—by C. L. Mueller to all counts, by J. J. Mueller, Jr., to dispensing *thyroid strong tablets*, and by M. Gengler to dispensing *pentobarbital sodium capsules*.

DISPOSITION: 9–14–56, C. L. Mueller fined $3,000 and J. J. Mueller, Jr., fined $1,000; 9–28–56, M. Gengler fined $500.

5107. (F. D. C. No. 38608. S. Nos. 12–307 M, 29–145 M.)

INFORMATION FILED: 6–15–56, Dist. N. J., against **Joseph S. Klausner, t/a Cornell Drug Co., Union City, N. J.**

CHARGE: On 12–13–55, *dextro-amphetamine sulfate capsules* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–9–56. Defendant placed on probation for 2 years.

5108. (F. D. C. No. 39363. S. Nos. 52–402/6 M, 52–462/3 M.)

INFORMATION FILED: 12–19–56, Dist. N. J., against **Grove Z. Ward, t/a Emmett Pharmacy, Newark, N. J.**

CHARGE: Between 4–18–56 and 4–24–56, *Dexedrine Sulfate tablets* were dispensed 4 times and *Seconal Sodium capsules* were dispensed twice without a prescription, and *Dexedrine Sulfate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 1–25–57. Fine of $700.

5109. (F. D. C. No. 39345. S. Nos. 30–351/6 M.)

INFORMATION FILED: 10–4–56, W. Dist. Tenn., against **Aud Earle Whayne (pharmacist and partner in Guthrie Pharmacy), Memphis, Tenn.**

CHARGE: Between 11–30–55 and 3–24–56, *Dexedrine Sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–26–56. Fine of $750.

5110. (F. D. C. No. 38580. S. Nos. 5–205/6 M, 5–208 M, 17–825 M, 17–884 M.)

INFORMATION FILED: 4–16–56, W. Dist. Mich., against **George P. Goulet, t/a Goulet's Drug Store, Greenville, Mich.**

CHARGE: Between 2–2–55 and 3–3–55, *Dexedrine Sulfate tablets* were dispensed twice, and *Metandren Linguets, Gantrisin tablets,* and *Tuinal pulvules* were each dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 5–11–56. Fine of $125.

5111. (F. D. C. No. 38583. S. Nos. 5–217/9 M, 17–824 M, 17–890 M.)

INFORMATION FILED: 4–16–56, W. Dist. Mich., against **Highfield Drug Co. (a corporation), Greenville, Mich., and H. Stewart Obersig and Lyle E. Paul (pharmacists).**

CHARGE: Between 2–15–55 and 3–3–55, *Dexedrine Sulfate tablets* (counts 1 and 4) were dispensed twice, and *Pentids tablets* (count 2), *Gantrisin tablets* (count 3), and *Metandren Linguets* (count 5) were each dispensed once, without a prescription.

PLEA: Guilty—by corporation to all 5 counts of information; by Obersig to counts 1 and 3; and by Paul to counts 2, 4, and 5.

DISPOSITION: 5–11–56. Corporation fined $125; Obersig, $50; and Paul, $75.

5112. (F. D. C. No. 39343. S. Nos. 47–654 M, 47–657 M, 48–374 M, 48–376 M, 48–378 M.)

INFORMATION FILED: 1–15–57, E. Dist. N. Y., against **Joseph Fried, t/a Fried's Pharmacy, Brooklyn, N. Y., and Benjamin Wolin (pharmacist).**

CHARGE: Between 3–1–56 and 3–28–56, *Dexedrine Sulfate tablets* and *Gantrisin tablets* were each dispensed once without a prescription, and *Bicillin tablets* were dispensed once and *Metandren Linguets* were dispensed twice upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by Fried to dispensing *Dexedrine Sulfate tablets, Gantrisin tablets, Bicillin tablets,* and *Metandren Linguets* once each, and by Wolin to dispensing *Metandren Linguets* once.

DISPOSITION: 2–14–57. Fried—$400 fine and probation for 1 year; Wolin—$100 fine and probation for 1 year.

5113. (F. D. C. No. 39380. S. Nos. 37–803/4 M, 37–812/13 M.)

INFORMATION FILED: 1–29–57, N. Dist. N. Y., against **Rothschild's Pharmacy (a partnership), Syracuse, N. Y., and Gustave Rothschild (partner) and Phillip Kaiser (pharmacist).**

CHARGE: Between 3–12–56 and 3–20–56, *Dexedrine Spansule capsules* (counts 1 and 3) and *capsules containing a mixture of secobarbital sodium, butabarbital sodium, and phenobarbital* (counts 2 and 4) were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by partnership to counts 1 and 2, by Rothschild to counts 1 and 2, and by Kaiser to counts 3 and 4.

DISPOSITION: 2–11–57. Partnership—$1,000 fine; Rothschild—$600 fine; and Kaiser—$200 fine.

5114. (F. D. C. No. 39360. S. Nos. 25–466/70 M.)

INFORMATION FILED: 11–27–56, E. Dist. Wash., against **Harry W. Tichacek, t/a Union Gap Pharmacy, Union Gap, Wash.**

CHARGE: Between 3–30–56 and 4–4–56, *Dexostan capsules* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1–11–57. Fine of $500.

5115. (F. D. C. No. 38629. S. Nos. 36–081 M, 36–104 M, 36–125/6 M, 40–081 M, 40–202 M.)

INFORMATION FILED: 6–21–56, E. Dist. Wis., against **Arthur C. Mehl, t/a Mehl's Drug Store, Milwaukee, Wis.**

CHARGE: Between 11–12–55 and 1–9–56, *penicillin G potassium tablets, amphetamine sulfate tablets,* and *pentobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10–1–56. Fine of $750.

5116. (F. D. C. No. 39192. S. Nos. 38–676/7 M, 38–679 M.)

INFORMATION FILED: 5–11–56, E. Dist. Mo., against **Elbert L. Dunn, t/a Dunn's Pharmacy, St. Louis, Mo., and John Victor Ruga.**

CHARGE: Between 3–28–56 and 3–29–56, *penicillin G potassium tablets, dextroamphetamine sulfate tablets,* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–27–56, Dunn—3-year jail sentence; 6–28–56, Ruga—3-year jail sentence.

5117. (F. D. C. No. 38593. S. Nos. 17–946/8 M, 35–737/8 M.)

INFORMATION FILED: 4–20–56, N. Dist. Ill., against **Latshaw's Pharmacy (a partnership), Chicago, Ill., and Jacob H. Lieberman (partner and pharmacist) and Milton Rappaport (partner and apprentice pharmacist).**

CHARGE: Between 7–19–55 and 8–9–55, *penicillin G potassium tablets* (count 3) were dispensed once and *penicillin G potassium troches* (counts 1 and 2) and *Gantrisin tablets* (counts 4 and 5) were each dispensed twice, without a prescription.

PLEA: Guilty—by corporation to all 5 counts of information; by Lieberman to count 1; and by Rappaport to counts 2, 3, 4, and 5.

DISPOSITION: 5–14–56. Partnership—$125 fine; Lieberman—$100 fine; Rappaport—$250 fine. Cost imposed against defendants jointly.

5118. (F. D. C. No. 38610. S. Nos. 18–751 M, 18–772 M, 18–775 M, 29–165 M.)

INFORMATION FILED: 11–2–56, S. Dist. N. Y., against **Samuel Langer, t/a Langer Pharmacy, New York, N. Y.**

CHARGE: Between 8–9–55 and 8–30–55, *Bicillin tablets, AM Plus capsules, Cortone Acetate tablets,* and *Gantrisin tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–16–56. Fine of $250; imposition of jail sentence suspended and defendant placed on probation for 2 years.

5119. (F. D. C. No. 39322. S. Nos. 39–032 M, 39–035/6 M.)

INFORMATION FILED: 7–9–56, M. Dist. N. C., against **Eugene Mazzolini (a pharmacist for Yadkin Drug Store), Yadkinville, N. C.**

CHARGE: Between 2–13–56 and 2–21–56, *Pentids tablets* were dispensed twice and *Gantrisin tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–7–56. Fine of $1,000 and probation for 2 years.

5120. (F. D. C. No. 38634. S. Nos. 981 M, 1–427 M, 1–435 M, 27–953 M, 39–202/3 M.)

INFORMATION FILED: 2–13–57, N. Dist. Ga., against **Standard Pharmacy, Inc., Atlanta, Ga., and John L. Stephens (vice president and treasurer).**

CHARGE: Between 9–6–55 and 1–13–56, *Gantrisin tablets* were dispensed twice without a prescription, and *Dexedrine Sulfate tablets* and *Nembutal capsules* were each dispensed twice upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 2–20–57. Corporation—$1,000 fine; individual—6-month jail sentence deferred and probation for 2 years.

5121. (F. D. C. No. 38586. S. Nos. 29–582 M, 30–089 M.)

INFORMATION FILED: 3–30–56, S. Dist. N. Y., against **Barnett Plattor, t/a Mohegan Pharmacy, Mohegan Lake, N. Y.**

CHARGE: Between 8–16–55 and 8–23–55, *Gantrisin tablets* and *Dexedrine Sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–24–56. Fine of $1,000.

5122. (F. D. C. No. 38618. S. No. 21–918 M.)

INFORMATION FILED: 6–11–56, N. Dist. N. Y., against **H. George Metz, t/a Rosenberg's Pharmacy, Syracuse, N. Y., and Jacob Rosenberg (pharmacist).**

CHARGE: On 11–7–55, *Gantrisin tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 1–14–57. Metz—$1,000 fine; Rosenberg—$900 fine.

5123. (F. D. C. No. 38619. S. Nos. 47–516/7 M, 47–519 M, 48–286/8 M, 48–292 M, 48–296 M.)

INFORMATION FILED: 11–15–56, S. Dist. N. Y., against **Murray Tittler, t/a Murray Pharmacy, New York, N. Y.**

CHARGE: Between 1–9–56 and 1–31–56, *Metandren Linguets* were dispensed twice and *Benzedrine Sulfate tablets* and *pentobarbital sodium capsules* were each dispensed 3 times, without a prescription.

PLEA: Guilty.

DISPOSITION: 11–27–56. Imposition of sentence suspended and defendant placed on probation for 2 years.

5124. (F. D. C. No. 38582. S. Nos. 5–213/6 M, 17–893 M.)

INFORMATION FILED: 4–16–56, W. Dist. Mich., against **O'Donald Pharmacy (a partnership), Greenville, Mich., and Charles S. O'Donald (partner) and John J. Snyder (pharmacist).**

CHARGE: Between 2–15–55 and 3–2–55, *Metandren Linguets* (counts 1 and 3) and *Dexedrine Sulfate tablets* (counts 2 and 5) were dispensed twice and *Gantrisin tablets* (count 4) were dispensed once, without a prescription.

PLEA: Guilty—by partnership to all 5 counts of information; by O'Donald to counts 1 and 3; and by Snyder to counts 2, 4, and 5.

DISPOSITION: 5–11–56. Partnership fined $125; O'Donald, $50; and Synder, $75.

5125. (F. D. C. No. 38581. S. Nos. 5–209/12 M, 17–822 M, 17–888 M.)

INFORMATION FILED: 4–16–56, W. Dist. Mich., against **Owen C. Mumaw, t/a Owen's Cut Rate Drugs, Greenville, Mich., and Paul V. Merren (pharmacist).**

CHARGE: Between 2–2–55 and 3–2–55, *Metandren Linguets* (counts 1 and 3) and *Dexedrine Sulfate tablets* (counts 2 and 4) were each dispensed twice and *Gantrisin tablets* (count 5) and *Tuinal pulvules* (count 6) were each dispensed once, without a prescription.

PLEA: Guilty—by Mumaw to all 6 counts of information and by Merren to counts 1, 4, and 6.

DISPOSITION: 5–11–56. Mumaw fined $150 and Merren $75.

5126. (F. D. C. No. 38579. S. Nos. 5–201/4 M, 17–881/2 M.)

INFORMATION FILED: 4–16–56, W. Dist. Mich., against **Ross L. Restorick, Greenville, Mich.**

CHARGE: Between 2–2–55 and 3–3–55, *Metandren Linguets, Dexedrine Spansule capsules, Gantrisin tablets, Metandren tablets, penicillin-bacitracin troches,* and *Tuinal pulvules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–11–56. Fine of $150.

5127. (F. D. C. No. 39205. S. Nos. 31–067 M, 37–601/3 M.)

INFORMATION FILED: 12–11–56, S. Dist. Ohio, against **Rinaldo D. Tarquinio, t/a Morris & Raymond Drug Store, Steubenville, Ohio.**

CHARGE: Between 3–30–56 and 4–24–56, *secobarbital sodium capsules* were dispensed 3 times and *amphetamine sulfate tablets* were dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 12–19–56. Defendant fined $400 and placed on probation for 3 years.

5128. F. D. C. No. 39344. S. Nos. 38–356 M, 38–359 M, 38–361 M.)

INFORMATION FILED: 8–22–56, E. Dist. Mo., against **Samuel DeLuca (pharmacist for DeLuca Drug), St. Louis, Mo.**

CHARGE: Between 3–28–56 and 4–5–56, *capsules containing a mixture of secobarbital sodium and amobarbital sodium, Dexedrine Sulfate tablets,* and *sulfathiazole tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITON: 11–20–56. Jail sentence of 30 days.

5129. (F. D. C. No. 39332. S. Nos. 37–797 M, 38–015 M.)

INFORMATION FILED: 8–2–56, N. Dist. N. Y., against **W. Barnard Skinner, t/a Skinner's Pharmacy, Syracuse, N. Y., and George W. Skinner (pharmacist).**

CHARGE: Between 10–31–55 and 1–12–56, *Seconal Sodium pulvules* and *dextro-amphetamine sulfate capsules* were each dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by W. B. Skinner to dispensing *dextro-amphetamine sulfate capsules* and by G. W. Skinner to dispensing *Seconal Sodium pulvules.*

DISPOSITION: 1–14–57. Fine of $900 against W. B. Skinner and $750 against G. W. Skinner.

5130. (F. D. C. No. 39348. S. Nos. 39-845/6 M, 39-848/9 M.)

INFORMATION FILED: 10-18-56, N. Dist. Ill., against **Polin-Lincoln Drug Co., Inc., Chicago, Ill., and Jeanette Polin (secretary).**

CHARGE: Between 4-9-56 and 4-16-56, *Seconal Sodium pulvules* and *amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11-5-56. Corporation—$100 fine, plus costs; individual—$200 fine.

5131. (F. D. C. No. 39369. S. Nos. 25-061/4 M.)

INFORMATION FILED: 12-31-56, Dist. Mont., against **Elmer T. Carkeek, t/a Jensen Drug Store, Butte, Mont., and Stanley H. Richards (employee).**

CHARGE: Between 3-22-56 and 3-29-56, *Seconal Sodium capsules* were dispensed 3 times without a prescription and once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by Carkeek to each of the 4 counts of the information and by Richards to 2 counts.

DISPOSITION: 1-10-57. Richards—$200 fine; jail sentence of 3 months suspended and probation for 1 year. Carkeek—$1,000 fine; jail sentence of 6 months suspended and probation for 1 year.

5132. (F. D. C. No. 39193. S. No. 20-541 M.)

INFORMATION FILED: 5-31-56, Dist. of Columbia, against **Jack Curzy, Washington, D. C.**

CHARGE: On 5-31-56, *Seconal Sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7-19-56. $500 fine or 1 year in jail.

5133. (F. D. C. No. 38620. S. No. 42-785 M.)

INFORMATION FILED: 8-18-56, N. Dist. Tex., against **Clem C. Primm, t/a Primm Drug Store, Brownfield, Tex., and James G. Riddle (pharmacist).**

CHARGE: On 11-8-55, *cortisone acetate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-7-56. Primm—$300 fine and probation for 3 years; Riddle—$100 fine and probation for 2 years.

5134. (F. D. C. No. 39354. S. Nos. 19-561 M, 19-569/70 M, 19-582 M, 30-705 M.)

INFORMATION FILED: 10-26-56, W. Dist. Ky., against **Estel K. Altman (pharmacist for Carpenter-Dent Drug Co.), Scottsville, Ky.**

CHARGE: Between 1-13-56 and 2-28-56, *cortisone acetate tablets* were dispensed 3 times and *penicillin G potassium tablets* were dispensed twice, without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11-12-56. $125 fine, plus costs.

5135. (F. D. C. No. 38621. S. Nos. 35-714 M, 35-719/20 M.)

INFORMATION FILED: 7-26-56, N. Dist. Ill., against **Lake Shore Pharmacy, Inc., Chicago, Ill., and Adolph E. Stein (president, manager, and pharmacist).**

CHARGE: Between 8-15-55 and 8-25-55, *Aureomycin capsules* were dispensed once and *Metandren Linguets* were dispensed twice, without a prescription.

PLEA: Guilty.

DISPOSITION: 9-28-56. Corporation—$300 fine; Stein—$300 fine. Costs of $39 against both defendants.

5136. (F. D. C. No. 38622. S. No. 42-781 M.)

INFORMATION FILED: 8-18-56, N. Dist. Tex., against **Clarence Gosdin, t/a Gosdin Drug Store, Brownfield, Tex.**

CHARGE: On 11-8-55, *Meticorten tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-7-56. $300 fine and probation for 3 years.

5137. (F. D. C. No. 38637. S. Nos. 34-076/9 M.)

INDICTMENT RETURNED: 8-21-56, E. Dist. Okla., against **Floyd L. Rice, Madill, Okla.**

CHARGE: Between 2-1-56 and 2-3-56, *Ipral calcium tablets* and *Doriden tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10-18-56. Jail sentence of 1 year and 1 day.

5138. (F. D. C. No. 38612. S. Nos. 42-446 M, 42-794 M.)

INFORMATION FILED: 8-15-56, N. Dist. Tex., against **Lubbock Drug Store (a partnership), Lubbock, Tex., and Clyde Harris and Earl Sledge (pharmacists).**

CHARGE: Between 11-14-55 and 11-16-55, *thyroid tablets* were dispensed twice without a prescription.

PLEA: Guilty—by partnership and Harris to one count and by Sledge to the other count.

DISPOSITION: 11-6-56. Partnership—$500 fine. Individuals—$200 fine each; imposition of prison sentences suspended and each placed on probation for 3 years.

5139. (F. D. C. No. 38635. S. Nos. 27-848 M, 27-856 M, 27-858 M.)

INFORMATION FILED: 8-10-56, W. Dist. N. C., against **Francis Muratori (pharmacist for Center Pharmacy), Charlotte, N. C.**

CHARGE: Between 9-2-55 and 9-27-55, *Premarin tablets* were dispensed once and *methyltestosterone sublingual tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10-4-56. $500 fine and probation for 2 years.

5140. (F. D. C. No. 38153. S. Nos. 13-217/8 M.)

INDICTMENT RETURNED: 1-25-56, E. Dist. Pa., against **Isadore Arthur Shenk, t/a Garden Pharmacy, Philadelphia, Pa.**

CHARGE: Between 2-23-55 and 2-25-55, *capsules containing ergot and apiol* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-29-56. $2,000 fine; imprisonment for 2 years suspended and defendant placed on probation for 5 years.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1958

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5141–5160

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They relate to drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. Also involved is the refusal to permit inspection, as authorized by Section 704. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) criminal proceedings which were terminated with a plea or verdict of guilty or a plea of nolo contendere; (3) injunction proceedings terminated with the entry of an injunction; (4) proceedings for violation of probation, which were terminated upon a finding of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation; and the criminal, injunction, and violation of probation proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *April 30, 1958.*

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SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5141–5160

Adulteration, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity and quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

5141. Terramycin capsules and tablets, Meticortelone tablets, and cortisone acetate tablets. (F. D. C. No. 39628. S. Nos. 52–413 M, 52–415/8 M.)

QUANTITY: 360 *Terramycin capsules* in 1 bag, 100 *Terramycin capsules* in 1 btl., and 3 100-tablet btls. of *Terramycin tablets;* 1 85-tablet btl. of *Meticortelone tablets;* and 1 25-tablet vial of *cortisone acetate tablets* at Brooklyn, N. Y.

SHIPPED: At various times, from Groton, Conn., Bloomfield, N. J., and Philadelphia, Pa.

RESULTS OF INVESTIGATION: The *Meticortelone tablets*, after shipment, had been repackaged and relabeled by the dealer, Bedford Surgical Co., Inc., Brooklyn, N. Y., under its own labels.

LIBELED: 10–5–56, E. Dist. N. Y.

CHARGE: 501 (c)—while held for sale, the strength of the *Terramycin tablets* differed from that which they were represented to possess (the tablets contained less than the declared amount of 250 mg. of *Terramycin* per tablet); 502 (b) (2)—while held for sale, the *Terramycin capsules* (1-bag lot) and the *Terramycin tablets* failed to bear labels containing accurate statements of the quantity of contents; 502 (e) (1)—while held for sale, the label of the *Terramycin capsules* (1-bag lot) failed to bear the common or usual name of the drug; 502 (f) (1)—the labelings of all of the articles, while held for sale, failed to bear adequate directions for use, and the articles were not

entitled to any exemption from such requirement; and 503 (b) (4)—all of the articles were drugs subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505 (a)—the repackaged and relabeled *meticortelone tablets* were a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11–26–56. Default—destruction.

DRUG FOR VETERINARY USE

5142. Acthone gel (veterinary). (F. D. C. No. 39929. S. No. 58–623 M.)

QUANTITY: 97 5-cc. vials at Denver, Colo.

SHIPPED: Between 9–1–56 and 9–6–56, from San Francisco, Calif., by Borden Laboratory.

LABEL IN PART: (Vial) "Borden Acthone (Veterinary) Gel * * * 40 U. S. P. Corticotropin Units."

LIBELED: 1–30–57, Dist. Colo.

CHARGE: 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 3–22–57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5143. Herb tonics, cold salve, and laxative tablets. (F. D. C. No. 38515. S. Nos. 14–410/1 M, 14–414 M, 14–417 M, 14–426 M, 14–470/3 M, 14–581 M, 30–148 M.)

INDICTMENT RETURNED: 3–8–56, E. Dist. Ill., against William H. Cruez. t/a East Side Herb Co., East St. Louis, Ill.

ALLEGED VIOLATION: Between 2–23–55 and 8–1–55, the defendant caused to be introduced into interstate commerce at East St. Louis, Ill., for delivery into the State of Missouri, quantities of various drugs which were labeled and misbranded as described below.

On 5–18–55, the defendant unlawfully refused entry and inspection of his establishment at East St. Louis, Ill., after having been presented by inspectors of the Food and Drug Administration with appropriate credentials and a written notice at a reasonable time, in accordance with the provisions of Section 704.

LABEL IN PART: "Herb Tonic Formula No. 1 Active Ingredients Punich, Granatum, and Pest Root"; "Herb Tonic Formula No. 3 Active Ingredients Quaking Aspen, Pride Weed, and Lucerne"; "Herb Tonic Formula No. 4 Active Ingredients Prickly Ash, Tansy Herb, Button Bush Bark and Elder Bark"; "Cold Salve" (examination showed that it contained, chiefly, petrolatum and smaller amounts of menthol and eucalyptol); and "Tablets Formula No. 556 Active Ingredients: Cascarin one-fourth grain, Aloin one-fourth grain, Podophyllin one-sixth grain, Extr. Belladonna one-eighth grain, Gingerine one-sixteenth grain. Distributed by Indiana Botanic Gardens, Hammond, Indiana."

*See also No. 5141.

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases for which the articles were recommended orally by the defendant, namely, (Formula No. 1 and Formula No. 556) ulcers, (Formula No. 3 and cold salve) arthritis, and (Formula No. 4) diabetes.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 6–11–56. On 6–20–56, after consideration of the evidence and briefs of counsel, the court handed down its findings of fact, conclusions of law, and verdict of guilty, as reported in 144 F. Supp. 229. On 6–27–56, the court fined the defendant $2,000, sentenced him to serve 1 year and 1 day in prison, and placed him on probation for a period of 5 years, to begin upon his release from prison.

5144. Tryptacin tablets. (F. D. C. No. 35585. S. Nos. 19–876 L, 39–562 L, 43–165 L, 48–106 L, 64–364 L, 72–361 L.)

INDICTMENT RETURNED: 3–1–55, N. Dist. Ohio, against Rhodes Pharmacal Co., Inc., Cleveland, Ohio, J. Sanford Rose, president, and Jerome H. Rose, vice president and treasurer, of the corporation.

SHIPPED: Between 9–18–52 and 9–29–53, from Ohio to Minnesota, West Virginia, Louisiana, Washington, and California.

LABEL IN PART: (Btl.) "Tryptacin RHODES * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

RESULTS OF INVESTIGATION: The article was represented in its advertising for use in the treatment of stomach ulcers.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since its labeling failed to state all of the conditions and diseases for which the article was intended to be used and was offered to the public in its advertising, and since the labeling of the article failed also to state the dosage and frequency and duration of administration for the treatment and prevention of such conditions and diseases.

PLEA: Guilty—by corporation; nolo contendere by individuals.

DISPOSITION: 6–29–56. Corporation fined $5,500; individuals placed on probation for 3 years.

5145. Dextro-amphetamine sulfate tablets. (F. D. C. No. 39204. S. Nos. 18–962 M, 19–483/4 M, 19–486/7 M, 23–854 M, 30–682 M, 31–060 M.)

INFORMATION FILED: 12–11–56, S. Dist. Ohio, against Ace Tablet Co., a partnership, Steubenville, Ohio, and Rinaldo D. Tarquinio, partner.

SHIPPED: Between 10–12–55 and 3–17–56, from Ohio to Arizona, Tennessee, and Kentucky.

LABEL IN PART: (Btl.) "Tablets Dextro Amphetamine Sulfate 5 Mg. Caution: Federal law prohibits dispensing without a prescription."

RESULTS OF INVESTIGATION: The tablets were shipped to persons who were not authorized to receive them.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

PLEA: Guilty.

DISPOSITION: 12–19–56. Defendant fined $800 and placed on probation for 3 years.

5146. Gassup. (F. D. C. No. 39297. S. No. 48–342 M.)

QUANTITY: 643 2-oz. btls. in 4 cases at Newark, N. J.

SHIPPED: 6–20–55, from Brooklyn, N. Y., by Manhattan Drug Co.

LABEL IN PART: (Btl.) "Gassup * * * Active Ingredients Magnesium Trisilicate * * * Gastom Chemical Company, Newark, New Jersey."

ACCOMPANYING LABELING: Leaflet designated "Gassup * * * Indicated in the treatment of Acidity."

LIBELED: On or about 7–18–56, Dist. N. J.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an effective treatment for indigestion and autointoxication; that it would relieve the pain of hemorrhoids; that it would prevent rheumatism; that it would reduce the accumulation of fat in the body, relieve headaches and dizziness, and prevent colds; that it would restore normal metabolism in the body; and that it was safe and suitable for continuous use; and 502 (f) (2)—the labeling of the article failed to bear a warning that frequent or continued use might lead to a dependence on laxatives.

DISPOSITION: 8–22–56. Default—destruction.

5147. Monazite sand. (Inj. No. 292.)

COMPLAINT FOR INFORMATION FILED: 11–1–55, W. Dist. Wash., against Raco, Inc., Seattle, Wash., and George Kosmos, president of the corporation.

LABEL IN PART: (Pad) "Cosmos Radioactive Pad * * * Place Pad Under Pillow or Mattress."

ACCOMPANYING LABELING: Placards entitled "The Radioactive Material in the Cosmos Radioactive Pad," "Arthritis? Bursitis?" and "Idaho Bursitis? Rheumatism? * * * Get the Cosmos Pad"; "blowup" photographs of an article entitled "Now—An Atomic Drugstore" taken from the January 21, 1955, issue of Colliers Magazine; copies of the January 21, 1955, issue of Colliers Magazine; leather-bound ring binders containing testimonial letters; and circulars entitled "Arthritis Bursitis Rheumatism."

CHARGE: The complaint alleged that the defendants caused an article known as *monazite sand* to be brought in bulk to Seattle, Wash., from places outside the State of Washington and to be packaged into pads labeled as described above; that, while the defendants held the sand and the pads for sale at Seattle, Wash., they caused such articles to be accompanied by the above-mentioned labeling and to be introduced into interstate commerce accompanied by such labeling.

The complaint alleged also that the articles, when introduced into interstate commerce, when received in interstate commerce, and while held for sale after shipment in interstate commerce, were misbranded as follows:

502 (a)—the labeling contained false and misleading representations that the articles provided an adequate and effective treatment for arthritis, bursitis, rheumatism, neuritis, and sinus trouble, and soreness of hands, wrists, forearms, and back; and

502 (f) (1)—the labeling did not bear adequate directions for use because it did not state all of the purposes and conditions for which the articles were intended.

DISPOSITION: 3–9–56. The defendants having consented, the court entered a decree of permanent injunction enjoining the defendants against doing the following acts with respect to the "Cosmos Radioactive Pad," the *monazite sand* which is a component of such pad, and any similar article or component, part or accessory thereof:

(a) causing to be introduced and delivered for introduction into interstate commerce any such articles which are misbranded within the meaning of 502 (a) because of any representation or suggestion in their labeling which conveys the false and misleading impression that such articles are beneficial in the treatment of arthritis, bursitis, rheumatism, neuritis, and sinus trouble, and soreness of hands, wrists, forearms, or back, or any other condition, and misbranded within the meaning of 502 (f) (1) because of the failure of the labeling to bear adequate directions in all of the conditions for which such articles are intended;

(b) receiving in interstate commerce and delivering or proffering delivery for pay or otherwise any of such articles which are misbranded under 502 (a) and 502 (f) (1), as specified above; and

(c) causing the association of labeling with any such articles or making any claim for such articles in any other manner while such articles are held for sale after shipment in interstate commerce, which results in the articles being misbranded under 502 (a) and 502 (f) (1), as specified above.

5148. Supplement to notice of judgment on drugs and devices, No. 4259. Ko-rekT dental device. (F. D. C. No. 33788. S. Nos. 33–667 L, 46–538 L.)

VIOLATION OF PROBATION: On 12–3–54, an application was filed for revocation of probation imposed against Demetrie C. Siampaus, the defendant in the case reported in the above-mentioned notice of judgment. It was alleged in the application that the defendant had shipped from Omaha, Nebr., to Sioux City, Iowa, a *Ko-rekT dental device* which was misbranded as follows:

502 (a)—the labeling of the device contained false and misleading representations similar to those which were the basis of the case in which the defendant was convicted; and

502 (f)1—the labeling failed to bear adequate directions for use of the device for the conditions set forth in a Sioux City newspaper advertisement sponsored by the defendant.

DISPOSITION: A hearing in the matter was held on 1–28–55, at which time the court continued the case for 6 months in order to enable the defendant to comply with the labeling requirements of the law.

Subsequent investigation showed that the defendant was continuing to violate the law, and on 7–2–55, after further hearing, the defendant was sentenced to 30 days in jail for violation of probation. The defendant filed a motion for rehearing. On 8–18–55, the court overruled the motion but continued the case for a period not in excess of 6 months and placed the defendant on probation during that period without requiring him to serve the jail sentence. On 2–9–56, a final hearing in the matter was held, at which time the court extended the probation for 6 months.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5149. Testosterone, desoxycorticosterone acetate, and progesterone. (F. D. C. No. 38566. S. Nos. 3–583 M, 8–859 M, 8–871 M.)

INFORMATION FILED: 5–21–56, S. Dist. Calif., against Coast Chemical Co., a corporation, and Cleo O. Bedwell, president.

SHIPPED: Between 11–9–54 and 2–1–55, from California to Arizona and Massachusetts.

LABEL IN PART: (Btl.) "10 cc Sterile Multiple Dose Vial Testosterone Crystalline U. S. P. In Aqueous Macrosuspension 50 Mgs. per cc Preservative: Merthiolate—1:20 M For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription. Made especially for Star Pharmacy, Wholesale Division Boston & Cambridge 39, Mass.," "10 cc Sterile Desoxycorticosterone Acetate U. S. P. Aqueous Macrosuspension of Desoxycorticosterone Acetate 5 mgs. per cc When Properly Shaken Purified Crystalline Adrenal Cortical Hormone preparation. Coast Pharmaceuticals Division of Coast Chemical Co. Los Angeles California," "Lot No. 5997 Caution: Federal law prohibits dispensing without prescription. For Intramuscular Injection Only," and "10 cc Sterile Progesterone U. S. P. In Aqueous Macrosuspension When properly shaken, each cc contains: Progesterone 50 mgs. (50 I. U.) Preservative: Merthiolate—1:20 M For Intramuscular Use Only Distributed by Rocky Mountain Pharmacal Co. Phoenix, Arizona * * * Caution: Federal law prohibits dispensing without prescription."

CHARGE: 501 (c)—when shipped, the purity and quality of the *testosterone* and *desoxycorticosterone acetate* fell below that which they were represented to possess in that these articles were represented to be sterile, whereas they were not sterile but were contaminated with viable micro-organisms; and 502 (a)—the word "Sterile" in the labeling of the *progesterone* was false and misleading since the article was not sterile but was contaminated with viable micro-organisms.

PLEA: Nolo contendere.

DISPOSITION: 8–1–56. Corporation fined $450 and individual $225. Corporation also placed on probation for 1 year.

5150. Dexatal tablets (Gracital). (F. D. C. No. 39243. S. No. 22–883 M.)

QUANTITY: 400 100-tablet btls. at Meriden, Conn.

SHIPPED: 10–6–55, from Worcester, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "Product No. 10 Graco Gracital Dextro Amphetamine Sulfate and Amobarbital C. T. Caution: Federal law prohibits dispensing without prescription * * * Each tablet contains: Dextro Amphetamine Sulfate, 5 mg. * * * Note: New Product Name Gracital Formerly Called Dexatal."

RESULTS OF INVESTIGATION: Examination showed that the article contained no significant amount of dextro-amphetamine sulfate.

LIBELED: 5–23–56, Dist. Conn.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 5 mg. of dextro-amphetamine sulfate; and

*See also No. 5141.

502 (a)—the labeling of the article contained the false and misleading statement "Each tablet contains: Dextro Amphetamine Sulfate 5 Mg."

DISPOSITION: 8–27–56. Consent—destruction.

5151. Elixir Cena-B. (F. D. C. No. 38957. S. No. 47–455 M.)

QUANTITY: 52 1-pt. btls. and 4 1-gal. btls. at Irvington, N. J.

SHIPPED: 1–21–56, from Long Island City, N. Y., by Ormont Drug & Chemical Co., Inc.

LABEL IN PART: (Btl.) "Elixir Cena-B Alcohol 21% By Volume."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially more than the declared amount of phenobarbital.

LIBELED: 2–20–56, Dist. N. J.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each 5 cc (1 Teaspoonful) Contains: Phenobarbital (¼ Gr.). . . . 16.0 Mg." was false and misleading.

DISPOSITION: 3–27–56. Default—destruction.

5152. Rauwolfia serpentina (powder and tablets). (F. D. C. No. 37372. S. Nos. 84–971 L, 84–973 L.)

QUANTITY: 1 drum containing 119 lbs., 1 drum containing 110¼ lbs., and 100,000 tablets at Philadelphia, Pa.

SHIPPED: 9–15–54 and 10–22–54, from New York, N. Y., by Prentiss Drug & Chemical Co., Inc., and Fine Chemical Co.

RESULTS OF INVESTIGATION: The article (powder) was shipped to Philadelphia, Pa., and after its arrival, a portion of the bulk powder was used to prepare the above-mentioned tablets, each of which contained 100 mg. of the powder.

Examination of the article (powder and tablets) showed that it contained the ground root of a species of *Rauwolfia* other than *Rauwolfia serpentina.*

LIBELED: 11–24–54, E. Dist. Pa.

CHARGE: 501 (d) (2)—the article (powder and tablets) was represented as *Rauwolfia serpentina* when shipped, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part therefor; and 502 (a)—the designation "Rauwolfia Serpentina" on the drum labels of the article was false and misleading since such designation represented and suggested that the article consisted wholly of *Rauwolfia serpentina,* whereas such was not the case.

DISPOSITION: Gane & Ingram, Inc., New York, N. Y., appeared as claimant and filed an answer denying that the article was adulterated or misbranded. The case came on for trial before the court without a jury; and, at its conclusion, the court, on 1–28–56, entered a decree condemning the article and ordering its destruction.

5153. Citru-Mix. (F. D. C. No. 39047. S. No. 35–465 M.)

QUANTITY: 48 2-oz. jars at Richmond, Ind.

SHIPPED: During September 1950, from Grand Rapids, Mich.

LIBELED: 5–18–56, S. Dist. Ind.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 5 mg. of vita-

min B_1 per ounce; and 502 (a)—the label statement "Vitamin B_1 (* * * 5 Mgm. per ounce)" was false and misleading as applied to the article, which contained less than 5 mg. of vitamin B_1 per ounce.

DISPOSITION: 9–14–56. Default—destruction.

5154. Fer-A-Bin tablets. (F. D. C. No. 39568. S. No. 50–526 M.)

QUANTITY: S 1,000-tablet btls. and 9 100-tablet btls. at Los Angeles, Calif.

SHIPPED: 3–2–49, from Cedar Rapids, Iowa.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of thiamine chloride.

LIBELED: 9–17–56, S. Dist. Calif.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 1 mg. of thiamine chloride; and 502 (a)—the label statement "Each Tablet Contains * * * Thiamin Chloride . . . 1 mgm." was false and misleading.

DISPOSITION: 10–11–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5155. Herbal drugs. (Inj. No. 301.)

COMPLAINT FOR INJUNCTION FILED: 10–4–56, N. Dist. Ind., against Deonisie Daniel Chirila, t/a Naturopathic Health Clinic; Chirila Naturopathic Clinic; Dr. Chirila's Health Clinic; Chirila Health Clinic; Dr. Chirila, N. D., Foundation of Physical Medicine; Chirila's Foundation of Physical Medicine; Dr. Deonisie D. Chirila's Health Clinic; Chirila Naturopathic Sanitarium–Clinic; and Chirila Sanitarium, at Elkhart, Ind.

CHARGE: The complaint alleged that the defendant was engaged in the business of manufacturing, preparing, selling, and distributing in interstate commerce various *herbal drugs* for human ailments; that the defendant maintained at his place of business a stock of bulk raw materials consisting of drugs, herbs, oils, salves, and extracts compounds which were received from interstate sources and were for use in the manufacture of the above-mentioned *herbal drugs;* that in the sale and distribution in interstate commerce of the *herbal drugs*, the defendant employed two methods, as follows: (1) Upon receipt of orders for such drugs, the defendant would deliver the drugs to the post office at Elkhart, Ind., for shipment to the individual purchasers and (2) in the course of personal interviews at Elkhart, Ind., with prospective out-of-state customers, the defendant would make a diagnosis of the customers' diseases and conditions and offer to sell such customers one or more of the *herbal drugs* for use in the treatment of the diagnosed diseases and conditions; and that when the *herbal drugs* were so sold and delivered, the defendant caused the drugs to be accompanied by one or more of the following pieces of labeling: pamphlets entitled "Advance Knowledge of the Cause of Human Ailments—Their Diagnosis and Beneficial Methods of Treatment Aid," "Scientific Development of Diagnosis and Treatment of the Human Body," "The Human Body and Its Physical Make-Up in Health or Unhealth," and "Dr. Chirila's Exercises for General Health—Supplement To Nature's Advanced Physician Health Guide"; booklets entitled "The Iris-Feet-Physical Diagnosis Interpret-

*See also Nos. 5146–5154.

ing Book Aid—Copyright 1947," "Nature's Advanced Health Guide—Final Supplement to Nature's Advanced Physician Health Guide," "Dr. Deonisie Daniel Chirila's Practical and Experimentally Developed Herbal Formulas * * * For the Benefit of Those in Need or Concerned," and "Nature's Aid Advanced Health Guide"; brochures entitled "Fundamental Healing Aid and Health Guide" and "Dr. Deonisie D. Chirila, N. D., M. T. D., D. C. * * * Founder and Originator of The Formulas Outlined in this Monumental Brochure For The Body Cleansing and Healing Aid"; leaflets entitled "Failures and Misconceptions by Dr. Deonisie D. Chirila" and "Announcement—Dr. Chirila's New Herbal Compound Preparations as General Body Energizing and Mucus Cleansing Aid for Restoration of Health"; and form letters headed "Dear Friends: —No. 327 Purgative Medium," "Health News and Truth—Dear Folks and Friends," and "Dear Doctor and Fellow Practitioner."

The complaint alleged further that the *herbal drugs* were misbranded under 502 (a) because of false and misleading representations in their labeling that such drugs constituted adequate and effective treatments for various diseases, symptoms, and conditions, including one or more of the following: brain troubles, eye infirmities, epilepsy, nervous troubles, influenza, high blood pressure, apoplexy, toxic conditions, laryngitis, acute indigestion, Bright's disease, inflammation of the kidneys, gallbladder and bile duct irritations, tuberculosis, lung weakness, anemia, sores, blood poisoning, intestinal ulceration and inflammation, neuralgia, backache, liver trouble, malarial fever, biliousness, acidosis, rheumatism, gout, arthritis, cough, cold, and functional kidney weakness.

The complaint alleged also that the defendant was well aware that his activities were violative of the law; that inspections had been made of his business in April 1944 and April 1955; that he had been warned against the interstate shipment of misbranded drugs by a Notice of Hearing dated 7–27–55; and that investigations in March and April 1956 showed that he was still continuing to ship misbranded drugs.

DISPOSITION: 10–18–56. The defendant having consented to the entry of a decree, the court entered a decree of permanent injunction. The decree enjoined the defendant against causing to be introduced and delivered for introduction into interstate commerce (1) the *herbal drugs* described in the complaint for injunction, and labeled as adequate and effective treatments for the diseases and ailments alleged, and (2) any quantity or amount, in any combination, of the bulk raw materials then held in stock by the defendant and used by him in the manufacturing of any similar drugs or any drugs offered for similar purposes.

The decree enjoined also the defendant against (1) causing such drugs to be accompanied by the above-described pieces of labeling or any similar written, printed, or graphic matter; (2) causing such drugs to be misbranded under 502 (a) by false and misleading representations with respect to the therapeutic efficacy of such drugs; (3) causing such drugs to be misbranded under 502 (f) (1) by reason of the failure of their labelings to bear adequate directions for use; and (4) doing any act with respect to such drugs, while held for sale after shipment in interstate commerce, which would result in such drugs being misbranded under 502 (a) and 502 (f) (1).

5156. Ce-Kelp tablets. (F. D. C. No. 39266. S. No. 3–201 M.)

QUANTITY: 16 1,000-tablet btls. at Portsmouth, N. H.

SHIPPED: 4–5–56, from St. Petersburg, Fla., by Dental Research Co., Inc.

LABEL IN PART: (Btl.) "Ce Kelp A Vegetable Sea Food C–Kelp, tablets are made from cleaned, washed, machine dehydrated Ce-Kelp, a marine plant, and no other material or adulteration. All the minerals in Ce-Kelp tablets are in combined form as present in machine dehydrated Macrocystis-pyrifers."

ACCOMPANYING LABELING: Pamphlets entitled "Ce-Kelp A Vegetable Sea Food" and "To Your Health."

LIBELED: 6–4–56, Dist. N. H.

CHARGE: 502 (a)—the accompanying labeling of the article, when shipped, contained false and misleading representations that the article was effective in the treatment of obesity, thinness, dental decay, pyorrhea, arthritis, glandular malfunction, premature aging, and degenerative changes in the body; that the use of the article would compensate for all mineral deficiencies in the diet and would promote and insure health; and that there are differences of opinion concerning the nutritional value of the small quantities of minerals other than calcium, phosphorus, iron, and iodine which are provided by the recommended daily intake of the article.

DISPOSITION: 7–17–56. Default—destruction.

5157. Vi-Tab tablets. (F. D. C. No. 39257. S. No. 39–038 M.)

QUANTITY: 696 60-tablet btls. at Charlotte, N. C.

SHIPPED: 8–3–55, from Jackson, Miss., by Bonded Distributing Co., Inc.

LABEL IN PART: (Btl.) "Vi-Tab the tonic tablet Just Two Tablets Daily as a Dietary Food Supplement, Contains The Minimum Daily Requirements, Or More, Of All The Vitamins Whose Need In Human Nutrition Has Been Established. 17 Vitamins 13 Minerals In a natural base of Liver, Yeast, Alfalfa, Wheat Germ Oil and Prune Powder. 60 Tablets (30 day supply) * * * Two Tablets Daily Provide at Least * * * Vitamin B_1 (Thiamin Chloride) 3 times Minimum Daily Requirements. . . . 3 mgs."

ACCOMPANYING LABELING: Leaflet designated "Why Vitamins and Minerals Are Needed. Vi-Tab 'The Tonic In A Tablet'."

LIBELED: 5–28–56, W. Dist. N. C.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective to increase life span, delay senility, promote resistance to disease, prevent loss of weight, prevent dimness of vision, prevent nervous irritability, prevent nerve degeneration, prevent sore mouth, promote growth in chronically ill children, prevent skin hemorrhages, prevent swelling of legs, improve muscle tone, prevent sterility, prevent liver and kidney disorders, prevent tumors, prevent poor coordination, and to act as a general tonic.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–23–56. Default—destruction.

5158. Lane's diuretic compound and Lane's Formula No. 2. (F. D. C. No. 39037. S. Nos. 43–225/6 M.)

QUANTITY: 27 cartoned btls. of *Lane's diuretic compound* and 10 cartoned btls. of *Lane's Formula No. 2* at Memphis, Tenn.

SHIPPED: 8–1–55 and 9–6–55, from Dunedin, Fla., by L & H Drug Co., Inc.

LABEL IN PART: (Ctn. & btl.) "Lane's Diuretic Compound For Kidneys Alcohol 12.5% * * * Active Ingredients: Fluidextracts of Uva Ursi, Zea, Buchu,—Glycerol and pure lemon juice. * * * 4 fluid ounces" and "Lane's Formula No. 2 * * * Active Ingredients: Magnesium Sulfate Thiamin HCL (B_1), Fluid Extract Cascara Sagrada, Aromatic U. S. P. * * * 8 Fluid Ounces."

ACCOMPANYING LABELING: (Leaflet enclosed in each carton) "Lane's Famous Products."

LIBELED: 4–18–56, W. Dist. Tenn.

CHARGE: 502 (a)—the accompanying labeling of the articles, when shipped, contained false and misleading representations that *Lane's diuretic compound* was an adequate and effective treatment for kidney stones and that *Lane's Formula No. 2* was an adequate and effective treatment for gallstones.

DISPOSITION: 6–15–56. Default—destruction.

5159. Electronic devices. (F. D. C. No. 39275. S. Nos. 40–064/5 M.)

QUANTITY: 2 devices at Chicago, Ill.

SHIPPED: Between 7–13–55 and 10–16–55, from Detroit, Mich., by Colo Products, Inc.

LABEL IN PART: "Neu-Clear Therapy Electronic 'Condensator' Generating 'Fluid' Electricity" and " 'Holder's' Electronic-Oscillating 'Condensator' Generating 'Fluid' Electricity."

ACCOMPANYING LABELING: Booklet entitled "Holder's Electronic High-Frequency Condensator Operating Instructions" and leaflets entitled "Doctors Report On Holder's Electronic Condensator" and " 'Holder's' Electronic Oscillating Condensator."

RESULTS OF INVESTIGATION: The devices consisted of an electronic, high-voltage oscillator and a group of glass electrode applicators. The electrodes were gas-filled and produced a glow discharge during application. Radio frequencies emanating from the devices were of such low power and low frequency as to have negligible absorption in the body.

LIBELED: 6–12–56, N. Dist. Ill.

CHARGE: 502 (a)—the labeling accompanying the devices, when shipped, contained false and misleading representations that the devices were effective for locating trouble areas and toxic conditions and for determining the seriousness of the condition; for treating all body ailments, including ailments of the eyes, ears, throat, tonsils, teeth, face, heart, lungs, liver, gallbladder, kidneys, pancreas, spleen, stomach, bowels, anus, rectum, breasts, ovaries, uterus, vagina, cervix, brain, and frontal sinus; and for treating abcesses, anemia, arthritis, rheumatism, paralysis, hay fever, hemorrhoids, varicose veins, leg ulcers, multiple sclerosis, mucous colitis, malnutrition, pain, influenza, indigestion, head noises, and allergic conditions due to a large variety of products.

DISPOSITION: 7–11–56. Default—delivered to Food and Drug Administration.

DRUG FOR VETERINARY USE

5160. Beebe Water Wormer. (F. D. C. No. 38975. S. No. 21–158 M.)

QUANTITY: 96 4-oz. btls., 123 8-oz. btls., and 51 32-oz. btls. at Fremont, Nebr.

SHIPPED: Between 11–21–55 and 1–18–56, from St. Paul, Minn., by Beebe Laboratories, Inc.

LABEL IN PART: (Btl.) "Beebe Water Wormer * * * Active Ingredients: Piperazine Citrate 32% Inert Ingredients: Water and Coloring 68% Directions: For Chickens: Remove all sources of drinking water the night before treatment. Mix thoroughly two ounces (four tablespoonfuls) in five gallons of drinking water and allow birds to drink freely. Provide only the treated drinking water for one day when treating for round worms. Treats 800 birds of any age. For Pigs: Remove all sources of drinking water the night before treatment. Mix thoroughly two ounces (four tablespoonfuls) in five gallons of drinking water and allow pigs to drink freely. One day treatment is sufficient for eliminating round worms. Treats 100–125 pigs weighing 25–40 pounds each."

LIBELED: 3–9–56, Dist. Nebr.

CHARGE: 502 (a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article, when fed as directed, was an adequate and effective treatment for large roundworm infestation in chickens and pigs.

DISPOSITION: 4–18–56. Consent—claimed by Beebe Laboratories, Inc., St. Paul, Minn., and relabeled.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5141 TO 5160

PRODUCTS

[1] (5143) Prosecution contested.
[2] (5147, 5155) Injunction issued.

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5161–5200

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They relate to drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) criminal proceedings which were terminated with a plea of guilty or nolo contendere; (3) injunction proceedings terminated with the entry of an injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *June 12, 1958.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 5188, 5190; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5190; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5190; cosmetic, actionable under the drug provisions of the Act, No. 5161.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5161–5200

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality and purity fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of penicillin or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5161. Extar (liquid dentifrice). (F. D. C. No. 39412. S. No. 46–689 M.)

QUANTITY: 72 ctns., 6 btls. each, at Trenton, N. J.

SHIPPED: 6–14–56, from Philadelphia, Pa., by Extar Division, A. J. Parker Co.

LABEL IN PART: (Ctn.) "Extar"; (btl.) "Contents: 67 Gm. * * * Liquid Dentifrice."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 12 percent ethylenediaminetetra acetic acid, together with inorganic sodium phosphates.

LIBELED: 8–7–56, Dist. N. J.

CHARGE: 505 (a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 9–7–56. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

5162. Anchor Anti-Blote. (F. D. C. No. 39153. S. No. 25–958 M.)

QUANTITY: 40 2-lb. cans at Des Moines, Iowa.

SHIPPED: 6–1–56, from St. Joseph, Mo., by Anchor Serum Co.

LABEL IN PART: (Can) "500 Doses Anchor Anti-Blote A Bloat Preventive for Cattle Veterinary Use Only * * * Each 2 Pounds Contain: Active Ingredients: Procaine Penicillin G, 37,500,000 Units."

LIBELED: 7–6–56, S. Dist. Iowa.

CHARGE: 502 (l)—when shipped, the article contained penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law; and the article had not been exempted from requirements of certification by regulations.

DISPOSITION: 9–7–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5163. Dainty-Maid Service drug and device and Dainty-Maid Personal Powder (2 seizure actions). (F. D. C. No. 33575. S. Nos. 54–165 L, 54–167 L.)

QUANTITY: 84 pkgs. of *Dainty-Maid Service* and 35 ctns. of *Dainty-Maid Personal Powder* at Detroit, Mich.

SHIPPED: 6–4–52 and 7–7–52, from Middlefield, Conn., by Dainty Maid, Inc.

LABEL IN PART: (Pkg.) "Dainty-maid Service"; (ctn.) "Dainty-maid Personal Powder * * * Contains: Boric Acid, Zinc Sulfate, Salicylic Acid, Sodium Chloride and Tannic Acid."

ACCOMPANYING LABELING: Booklets entitled "Why must this crucial subject be Hush-Hush?" and "Profitable Suggestions For The New Dealer"; leaflets entitled "Here is an opportunity you can't afford to miss," "A Dignified Fascinating New Profession," and "Modern Heat Therapy"; charts entitled "Eight Reasons for Owning a Dainty-Maid Service"; and book entitled "Mary Coleman's Training Course In Personal Hygiene."

RESULTS OF INVESTIGATION: Each *Dainty-Maid Service* package contained 1 rubber douche bag, 1 porcelain vaginal syringe, 1 carton of *Dainty-Maid Personal Powder*, 2 pieces of rubber tubing, 1 rubber rectal tube, 1 glass "Earigator," 1 metal clamp, 1 plastic measuring scoop, and 1 leaflet entitled "Instructions."

LIBELED: 9–9–52, E. Dist. Mich.; amended 1–27–56.

CHARGE: 502 (a)—when shipped, the labeling of the articles contained false and misleading representations that the articles provided an adequate and effective treatment for preventing women from fading early in life and becoming nagging, irritable, cruel, emaciated, and scrawny; for preventing rough and pimpled skins, wrinkles on young faces, headaches, tiredness, enervation, and constant fatigue; for providing a buoyant, vibrant life; for increased vaginal discharge, leucorrhea, *Trichomonas vaginalis*, nonspecific vaginitis, and pelvic inflammatory conditions; for providing increased circulation of the blood throughout the entire body; for diseased organs, painful menstruation, and inflammation of the bladder; for stimulating the circulation, so that the glands function naturally; for minimizing "hot flashes" in older women, combatting all kinds and conditions of feminine disorders, and clearing up and preventing the occurrence of many of the most distressing of women's diseases and deplorable aftereffects; for menopausal symptoms, such as "hot flashes," nervous irritability, peevishness, and depressions; for senile vaginitis, painful menstruation, and profuse menstruation; for preventing and destroying ovarian cysts; and for falling of the womb, anteversion

of the womb, retroversion of the womb, and chronic bladder ailments; and that the articles were safe for frequent and even daily use as a douche; and 502 (f) (1)—the articles, when shipped and while held for sale, failed to bear adequate directions for use in the conditions for which they were intended, namely, the conditions hereinbefore described.

DISPOSITION: Dainty Maid, Inc., appeared as claimant and filed an answer to the libel, denying that the products were misbranded as alleged and asserting that only one proceeding was permissible under Section 304 (a), as the alleged misbranding in each of the proceedings had not been the basis of a prior judgment in favor of the United States; and, further, the Secretary had not found any of the circumstances that would permit multiple seizures.

The Government moved to strike the portions of the claimant's answer dealing with the multiple seizures' provision of the Act. The claimant then moved for dismissal of the libel or removal of the proceedings to the Southern District of New York, which was denied on March 9, 1954.

The claimant appealed from the above order to the United States Court of Appeals for the Sixth Circuit. The Government moved to dismiss the appeal, which motion was granted in the following opinion on November 19, 1954 (216 F. (2d) 668):

STEWART, *Circuit Judge:* "Proceeding under the Federal Food, Drug and Cosmetic Act, the United States filed two libels of information in the district court, seeking condemnation of a number of allegedly misbranded articles of device and drug and accompanying printed material. The statute forbids multiple seizures, permitting not more than one libel for condemnation based upon the same alleged misbranding, except '(1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction or libel for condemnation proceeding under this chapter, or (2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.' 21 U. S. C. A., § 334 (a).

"Appellant filed as claimant in each case and interposed answers, affirmatively asserting that the alleged misbranding in each of these proceedings had not been the basis of a prior judgment in favor of the United States, that the Secretary had not found any of the circumstances that would permit multiple seizures, and that consequently only one proceeding was permissible under the provisions of 21 U. S. C. A., § 334 (a).

"Appellee moved to strike these defenses, claiming that the alleged misbranding had been the basis of a prior judgment in favor of the United States entered in 1948 in the Middle District of Pennsylvania, entitled, United States of America v. 13 Sets More or Less of an Article of Drug and Device Labeled in part 'Dainty-Maid Service,' which appellant had permitted to go to judgment by default.

"It appears that the labeling which was the subject of this prior adjudication was similar to, but not identical with the alleged misbranding in the present proceedings.

"Appellant filed a cross-motion for an order dismissing the libels, or either of them, and it is from the district court's denial thereof that this appeal was taken. Appellee has moved to dismiss the appeal on the ground that the denial of a motion to dismiss a libel of information filed pursuant to the Federal Food, Drug and Cosmetic Act is not an appealable order.

"The question which appellant would have us now decide is whether the statute permits multiple seizures of allegedly misbranded articles when the prior adjudication in favor of the United States involves similar but not the same labeling.

"Appellant contends that the phrase 'such misbranding' in the statute was intended to and does mean 'the same misbranding,' and that multiple seizures are permissible only against the identical labeling as was the subject

of the prior adjudication. The question is a novel one, but we have concluded that it is prematurely before us, and that appellee's motion to dismiss this appeal must be granted.

"It is conceded that the order appealed from is not a final decision from which an appeal would lie under the provisions of 28 U. S. C., § 1291. Appellant points out, however, that § 334 (b) of the Federal Food, Drug and Cosmetic Act provides that the procedure in condemnation cases under the Act 'shall conform, as nearly as may be, to the procedure in admiralty'; 21 U. S. C. § 334 (b), and appellant rests this appeal upon 28 U. S. C., § 1292 (3) which gives us jurisdiction of appeals from 'interlocutory decrees of such district courts or the judges thereof determining the rights and liabilities of the parties to admiralty cases in which appeals from final decrees are allowed.' It is appellant's position that the statute conforming the procedure in this type of case 'as nearly as may be, to the procedure in admiralty,' requires that this appeal be governed by principles of appellate jurisdiction in admiralty, and that in admiralty such an order as is here involved would be appealable. We think both contentions are incorrect.

"In 443 Cans of Frozen Egg Product v. United States, 226 U. S. 172 (1912), the Supreme Court had before it the claim that an almost identical clause in the predecessor Food and Drug Act of 1906 operated to make appeals in condemnation cases under that Act subject to the statutes applicable to appeals in admiralty. The Supreme Court rejected the contention, saying, 'The Act makes no reference, in conforming the proceedings as near as may be to those in admiralty, to appellate procedure. It leaves that to be determined by the nature of the case and the statutes already in force. . . .

" 'We do not think it was intended to liken the proceedings to those in admiralty beyond the seizure of the property by process in rem, then giving the case the character of a law action, with trial by jury if demanded and with the review already obtaining in actions at law.' 226 U. S. 182, 183.

"Although the 443 Cans of Frozen Egg Product case was decided in a somewhat different context, we think the decision remains entirely valid under the existing statutes, and dictates rejection of appellant's argument.

"It may be added that even in admiralty it does not appear that the order here complained of would be an appealable one. The Maria, 67 F. (2d) 571 (C. A. 2, 1933); cf. Emerick v. Lambert, 187 F. (2d) 786, 788 (C. A. 6, 1951).

"The rights and liabilities of the parties in this case have not been finally determined by the order of the district court. Whether the misbranding here alleged is 'such misbranding' as was the basis of the prior judgment is primarily a factual question, and this court is not a trier of facts. The ends of justice will be better served by deferring review until after a hearing and final judgment in the district court on the merits. The parties are entitled, no less than we, to the benefit of a record containing factual findings and legal conclusions that can be intelligently reviewed on appeal.

"The motion to dismiss the appeal is granted."

The Government moved for Summary Judgment, which was denied on December 29, 1955. The Government then made a motion to amend the libels to include the above-mentioned charge of misbranding under Section 502 (f) (1), which motion was granted on January 27, 1956.

The case went on to trial, and on March 23, 1956, the jury returned a verdict for the Government.

On May 9, 1956, the court entered the following decree of condemnation:

LEVIN, *District Judge:* "These actions were commenced by the filing of two libels on September 9, 1952, in the United States District Court for the Eastern District of Michigan, Southern Division. Dainty Maid, Inc., of Middlefield, Connecticut, intervened and filed a claim of ownership and an answer. There being common questions of law and fact involved in both actions, the two actions were consolidated for trial; and upon claimant's demand for a jury trial, were tried before a jury beginning on March 20, 1956.

"Now the jury, having heard the evidence and entered a verdict in favor of the libellant, the United States of America, finding that the articles of drug and device seized herein were misbranded as alleged in the libels, it is hereby

"ORDERED, ADJUDGED, AND DECREED that the 84 packages, more or less, of an article of drug and device labeled in part 'Dainty-Maid Service' and accompanying labeling, and 35 cartons, more or less, of an article of drug labeled in part 'Dainty-Maid Personal Powder' and accompanying labeling, are hereby condemned pursuant to 21 U. S. C. 334 (a).

"The claimant, Dainty Maid, Inc., by its attorney, Arthur D. Herrick, having petitioned the court to deliver the condemned articles to the claimant for the purpose of relabeling under the provisions of 21 U. S. C. 334 (d), the court hereby denies said petition and orders that the condemned articles be destroyed by the United States Marshal for this district, provided that the Marshal is directed to deliver to a qualified representative of the Secretary of the Department of Health, Education, and Welfare, a quantity of the drugs, devices, and literature seized, for exhibit purposes.

"The court bases its order refusing to allow relabeling upon the following grounds:

"1. 21 U. S. C. 334 (d) provides that after entry of a decree of condemnation 'the court may by order direct that (the condemned) article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act. . . .' The court is of the opinion that this language reposes discretion in the court as to whether relabeling should be allowed.

"2. The identical drug and device involved in the present action was the subject of a prior condemnation proceeding in the United States District Court for the Middle District of Pennsylvania, which was determined on August 23, 1948, and in which it was found that the Dainty-Maid Service there involved was misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act because the article was falsely represented in its labeling as being effective in preventing leucorrhea and other conditions associated with a vaginal discharge.

"3. The labeling involved in the present case, which arose four years later, made similar representations that the Dainty-Maid Service would effectively prevent and treat leucorrhea, ovarian cysts, and a host of other conditions which give rise to a vaginal discharge. Such claims were made in all of the labeling associated with the condemned article including the booklet 'Why Must This Crucial Subject Be Hush-Hush?' The latter booklet, in particular, was a calculated and designed attempt to effectively make such unwarranted claims while appearing to disclaim such intention.

"4. Testimony at the trial by outstanding experts in the fields of gynecology, dermatology, internal medicine and pathology convincingly demonstrated that the Dainty-Maid Syringe and Powder would not be effective in treating or preventing the serious disease conditions for which it was recommended in its labeling. In fact, they testified that because of the pressure built up by the device when used as recommended, it presented a serious health hazard. They testified that when used as directed it could force fluid containing disease organisms into the cervical canal and fallopian tubes which could result in serious impairment to health. Furthermore, by persuading women suffering from conditions manifested by a vaginal discharge to forego proper medication, reliance upon this device and powder could cause the aggravation of diseases which must be treated promptly if a cure is to result.

"5. Both because of the danger to health involved through the use of this syringe and powder, and because of the flagrant misbranding which was continued despite a prior court decree finding that the claims were false and misleading, the motion for release of the seized articles for the purpose of relabeling is denied.

"WHEREFORE, the United States Marshal for this District is directed pursuant to 21 U. S. C. 334 (d) to dispose of the articles seized by appropriate destruction of the seized articles, except for ten of the Dainty-Maid Service kits which he is directed to turn over to a representative of the United States Food and Drug Administration for exhibit purposes."

On August 8, 1956, the court entered an order amending the decree of condemnation to provide for the delivery to the Food and Drug Administration of all the drugs, devices, and literature seized.

5164. Nutrilite food supplement. (F. D. C. No. 39346. S. No. 38-006 M.)

INFORMATION FILED: 10-12-56, N. Dist. Ohio, against Harold J. Kennedy, Youngstown, Ohio.

ALLEGED VIOLATION: On or about 1-26-56, the defendant, in the course of a sales talk to individuals, made oral representations that the article was an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the article being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Pkg.) "Nutrilite (R) XX Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, cerebral thrombosis, blood clots of the heart and brain, arthritis, arteriosclerosis, high blood pressure, hay fever, asthma, diabetes, headaches, emesis, ulcerated stomach, general run-down condition, cataracts, and cancer.

PLEA: Guilty.

DISPOSITION: 11-30-56. Defendant placed on probation for 6 months.

5165. Aserpon tablets. (F. D. C. No. 38946. S. No. 23-628 M.)

QUANTITY: 10 100-tablet labeled btls. and 15,000 unlabeled tablets at Boston, Mass., in possession of R. J. Moran Co.

SHIPPED: On 4-6-55, a concentrate of reserpine was shipped from Brooklyn, N. Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Btl.) "Aserpon 0.25 mg. Caution: Federal law prohibits dispensing without prescription * * * Each tablet contains Reserpine 0.25 mg."

RESULTS OF INVESTIGATION: Upon receipt of the reserpine concentrate by the consignee at Boston, Mass., the concentrate was processed into tablets.

The tablets made from the concentrate were regarded as a new drug. However, the label of the concentrate when shipped did not bear the statement provided by the regulations for bulk material intended for use in the manufacture of a new drug; and the labeling of the article did not bear adequate directions for use, nor was the concentrate exempt from bearing adequate directions for use.

LIBELED: 2-13-56, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use.

DISPOSITION: 6-4-56. Default—destruction.

5166. Myo-Flex device. (F. D. C. No. 38647. S. No. 10-820 M.)

QUANTITY: 2 devices at Dickinson, Tex.

SHIPPED: In March 1954 and July 1955, by Mr. E. B. Dodd, from Shreveport, La.

LABEL IN PART: (Device) "The Edwards Neurotheraphy Modality 'Myo-Flex'."

ACCOMPANYING LABELING: Booklet entitled "1955 Edition of the Basic Procedure for Operating The Automatic Neurotheraphy Modality: 'The Edwards Myo-Flex'."

RESULTS OF INVESTIGATION: The device consisted of a cabinet housing various switches, transformers, condensers, vacuum tubes, and other electrical parts. When connected to the ordinary household electric supply, the device provided various types of electrical current output capable of causing stimulation of human muscles.

LIBELED: 11–10–55, S. Dist. Tex.; libel amended 3–2–56.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article provided an adequate and effective treatment for abdominal adhesions, acroparesthesia, amenorrhea, partially ankylosed joints, arthritis, and partial ankylosis, asthma, atrophy (muscular), backache, bronchitis, contusions, subdeltoid bursitis (chronic), cerebral palsy, chilblains, constipation, deafness (chronic), depression, involutional depression, Dupuytren's contraction, dysmenorrhea, endocrine stimulation, epilepsy, eye conditions, headache, head colds, hemorrhoids, lumbago, menopause (hot flushes), medullar subshock, muscle spasm, menstrual pains, multiple sclerosis, muscle training, neuralgia, neurotic tension, paralysis, peripheral facial palsy (Bell's palsy), paralysis agitans, posterolateral sclerosis, prostatic hypertrophy, ptosis of the abdomen, Raynaud's disease, relaxed vaginal walls, rheumatism (chronic), sciatica, sinus conditions, hay fever, stomach conditions, Buerger's disease, trigeminal neuralgia, prolapse of uterus, visceroptosis, and wry neck; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use by laymen, and the device was not entitled to any exemption from the requirement of adequate directions for use since it was a prescription device and was not in the possession of a person legally entitled to employ it for medical purposes.

DISPOSITION: 7–24–56. Consent—claimed by Mr. E. B. Dodd, Dickinson, Tex.; relabeled and delivered to a licensed practitioner.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5167. Pan-Vita syrup. (F. D. C. No. 38617. S. No. 9–596 M.)

INFORMATION FILED: 7–31–56, N. Dist. Calif., against Barnes-Hind Laboratories, Inc., San Francisco and Sunnyvale, Calif.

ALLEGED VIOLATION: On 11–11–49, the defendant gave to a firm engaged in the business of shipping drugs in interstate commerce a guaranty to the effect that all drug products shipped by the defendant to the holder of the guaranty would be neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 10–13–55, the defendant shipped a number of bottles of adulterated and misbranded *Pan-Vita syrup* to the holder of the guaranty at Los Angeles, California.

CHARGE: 501 (c)—the strength of the article differed from, and the quality of the article fell below, that which it purported and was represented to possess; and 502 (a)—the label statement "Each two teaspoonfuls (10 cc) contain: Vitamin A Palmitate . . . 5000 USP. Units Vitamin D (irradiated ergosterol). . . 500 USP. Units" was false and misleading since the article contained less vitamin A and vitamin D than declared.

PLEA: Nolo contendere.

DISPOSITION: 8–10–56. Fine, $500.

5168. Cal-Fer-D tablets. (F. D. C. No. 38986. S. No. 22–974 M.)

QUANTITY: 34 100-tablet btls. at Boston, Mass., in possession of Pitman-Moore Co.

SHIPPED: 5–3–55, from Indianapolis, Ind.

LABEL IN PART: (Btl.) "Tablets Cal-Fer-D Coated Red Each tablet represents: * * * Vitamin D (Irradiated Ergosterol) . . . . 200 U. S. P. units."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of vitamin D.

LIBELED: 3–8–56, Dist. Mass.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each tablet represents: * * * Vitamin D (Irradiated Ergosterol) . . . 200 U. S. P. units" was false and misleading.

DISPOSITION: 6–19–56. Default—destruction.

5169. Magnesium carbonate. (F. D. C. No. 39281. S. No. 31–340 M.)

QUANTITY: 6 50-lb. bags at Cincinnati, Ohio.

SHIPPED: 4–11–56, from Philadelphia, Pa., by Darlington Chemicals, Inc.

LABEL IN PART: (Bag) "Magnesium Oxide Light Powder * * * Darlington Chemicals (Inc.) Philadelphia, Pa. Made in England"; (sticker) "DCI Magnesium Carbonate U. S. P."

RESULTS OF INVESTIGATION: Analysis showed that the article was magnesium oxide with a small amount of calcium oxide.

LIBELED: 6–18–56, S. Dist. Ohio.

CHARGE: 501 (d)—when shipped, magnesium oxide with a small amount of calcium oxide had been substituted for *magnesium carbonate*; and 502 (a)—the label statement "DCI Magnesium Carbonate U. S. P." was false and misleading.

DISPOSITION: 7–17–56. Default—destruction.

5170. Ephedrine sulfate. (F. D. C. No. 39006. S. No. 47–632 M.)

QUANTITY: 1 case containing 2 100-oz. cans, and 1 500-oz. drum at New York, N. Y.

SHIPPED: 1–31–56, from England.

RESULTS OF INVESTIGATION: The article was water-damaged in shipment.

LIBELED: 4–3–56, S. Dist. N. Y.

CHARGE: 501 (b), while held for sale, the quality and purity of the article fell below the standard set forth in the United States Pharmacopeia since the standard provides that *ephedrine sulfate* when dried at 105° for 3 hours, loses not more than 2 percent of its weight; whereas the article when dried at 105° for 3 hours, would lose substantially more than 2 percent of its weight because of excessive water content.

DISPOSITION: 4–24–56. Default—destruction.

5171. Digitalis tablets. (F. D. C. No. 38985. S. No. 23–877 M.)

QUANTITY: 1 drum containing 24,000 tablets at Tucson, Ariz.

SHIPPED: 12–29–55, from Denver, Colo., by Western Research Laboratories.

RESULTS OF INVESTIGATION: Analysis showed that the digitalis potency of the article was less than 85 percent of its declared potency of 1½ grains of U. S. P.

digitalis per tablet. The United States Pharmacopeia provides that the potency of digitalis calculated from the prescribed assay is satisfactory if the result is not less than 85 percent and not more than 120 percent of the labeled potency.

LIBELED: 3–14–56, Dist. Ariz.

CHARGE: 501 (b)—the strength of the article, when shipped, differed from the standard for such article as set forth in the U. S. Pharmacopeia; and 502 (a)—the label statement "Each Tablet Contains: Digitalis, U. S. P.—1½ gr." was false and misleading.

DISPOSITION: 4–30–56. Default—destruction.

5172. Digitalis tablets. (F. D. C. No. 39237. S. No. 37–667 M.)

QUANTITY: 12 1,000-tablet btls. and 2 500-tablet btls. at Buffalo, N. Y.

SHIPPED: 3–27–56, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

LABEL IN PART: "Digitalis 1½ grs. Myocardial Stimulant Each tablet represents Digitalis Leaf 1 U. S. P. Unit * * * Control 264–456 * * * Manufactured for Kloman Inst. Co., Inc. Buffalo, New York."

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce in bulk, and upon their receipt by the consignee, were repackaged and relabeled.

Analysis showed that the digitalis potency of the article fell below its professed potency.

LIBELED: 5–15–56, W. Dist. N. Y.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, "Digitalis Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, its strength and quality differed from the standard set forth in such compendium; and 502 (a)—the label statement "Digitalis 1½ grs." was false and misleading.

DISPOSITION: 6–20–56. Default—destruction.

5173. Thyroid tablets. (F. D. C. No. 39598. S. No. 55–326 M.)

QUANTITY: 5 5,000-tablet btls. and 28 1,000-tablet btls. at Columbus, Ohio.

SHIPPED: 12–29–55, from Memphis, Tenn., by Morton Pharmaceuticals, Inc.

LABEL IN PART: "Code No. 467 * * * Thyroid Tablets 1 Gr. Code No. 466 E. C. Orange Each Tablet Contains Thyroid 1 Gr. USP * * * Distributed By Standard Medical Supply Co. * * * Columbus, Ohio."

LIBELED: 10–17–56, S. Dist. Ohio.

CHARGE: 501 (b)—the article was represented as a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, it fell below the official standard of quality since it failed to comply with the U. S. P. disintegration test for tablets.

DISPOSITION: 11–21–56. Default—destruction.

5174. Velestron tablets. (F. D. C. No. 39447. S. No. 27–218 M.)

QUANTITY: 52 100-tablet btls. at Birmingham, Ala., in possession of Veltex Co.

SHIPPED: 2–29–56, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: (Btl.) "100 Tablets Velestron Conjugated Estrogens 1.25 Mg. * * * Each Sugar-Coated Brown Tablet Contains: Naturally-occur-

ring water soluble, Conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate."

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce in bulk drums under an invoice reading, in part, as follows: "Conjugated Estrogens 1.25 Mg. S. C. yellow oval. Each tablet contains: Naturally occurring water-soluble, conjugated forms of the mixed estrogens obtained from the urine of pregnant mares. The principal estrogen present is Sodium Estrone Sulfate with varying small amounts of other equine estrogens and relatively large quantities of Nonestrogenic material."

Upon receipt of the drums, the consignee repackaged the tablets into bottles labeled as described above. Analysis showed that the total estrogen content per tablet was equivalent to not more than 0.92 mg. of sodium estrone sulfate.

LIBELED: 8–27–56, N. Dist. Ala.

CHARGE: 501 (c)—the strength of the article, when shipped and while held for sale, differed from that which it purported and was represented to possess, namely, an amount of estrogens in each tablet equivalent to 1.25 mg. of sodium estrone sulfate; and 502 (a)—while held for sale, the label statement "Each Sugar-Coated Brown Tablet Contains: Naturally-occurring water soluble, Conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate" was false and misleading.

DISPOSITION: 9–27–56. Default—destruction.

5175. Orapin tablets. (F. D. C. No. 39282. S. Nos. 38–883/5 M.)

QUANTITY: 1 23,000-tablet btl., 109 100-tablet btls., and 6 500-tablet btls. at Sarasota, Fla., in possession of Still Co., Inc., t/a Stillco Laboratories.

SHIPPED: 2–25–55, from Brooklyn, N. Y.

LABEL IN PART: (Btls.) "No. 154 Orapin 0.300 mgm. Conjugated Estrogens," "No. 148 Orapin 0.625 mgm. Conjugated Estrogens," or "No. 146 Orapin 1.25 mgm. Conjugated Estrogens."

RESULTS OF INVESTIGATION: Analyses showed that the tablets contained conjugated estrogens equivalent to (No. 154) 0.21 mg., (No. 148) 0.39 mg., and (No. 146) 0.78 mg. of sodium estrone sulfate per tablet.

LIBELED: 7–2–56, S. Dist. Fla.

CHARGE: 501 (c)—the strength of the tablets, while held for sale, differed from that which they purported and were represented to possess; and 502 (a)—the label statements (No. 154) "Each tablet contains conjugated estrogens equivalent to 0.300 mgm. of Sodium Estrone Sulphate," (No. 148) "Each tablet contains conjugated estrogens equivalent to 0.625 mgm. of Sodium Estrone Sulphate," and (No. 146) "Each tablet contains conjugated estrogens equivalent to 1.25 mgm. of Sodium Estrone Sulphate" were false and misleading.

DISPOSITION: 9–20–56. Default—destruction.

5176. Adhesive bandages. (F. D. C. No. 39411. S. No. 28–701 M.)

QUANTITY: 2 ctns., each containing 49 boxes, at San Francisco, Calif.

SHIPPED: 12–28–55, from Buffalo, N. Y., by United States Plastic Bandage Co.

LABEL IN PART: (Box) "Contains 100 Bandages ¾'' x 3'' Elast Aids Pliable Plastic Bandages * * * Sterility guaranteed—unless envelope opened."

LIBELED: 8–7–56, N. Dist. Calif.

CHARGE: 501 (b)—the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and when shipped, its quality and purity fell below the official standard since the article was not sterile but was contaminated with viable micro-organisms.

DISPOSITION: 10–23–56. Default—destruction.

5177. Fingertip dressings. (F. D. C. No. 39490. S. No. 25–441 M.)

QUANTITY: 18 boxes, each containing 100 bandages, at Seattle, Wash.

SHIPPED: 1–30–56 and 3–3–56, from Buffalo, N. Y., by United States Plastic Bandage Co.

LABEL IN PART: (Wrapper) "Elast Aid Form-Cut fingertip dressings * * * Sterility Guaranteed Unless Envelope Opened U. S. Plastic Bandage Co. Buffalo, N. Y."

LIBELED: 10–1–56, W. Dist. Wash.

CHARGE: 501 (b)—the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the quality and purity of the article, when shipped, fell below the official standard since the article was not sterile.

DISPOSITION: 12–20–56. Default—destruction.

5178. First aid kits. (F. D. C. No. 39443. S. No. 31–311 M.)

QUANTITY: 257 *first aid kits* at Toledo, Ohio.

SHIPPED: 2–13–56, from Tulsa, Okla.

LABEL IN PART: (Btl.) "100 Water Purification Tablets * * * Halazone * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with Sodium Borate and Chloride [or "with Sodium Carbonate, Sodium Chloride and Boric Acid"]."

RESULTS OF INVESTIGATION: Examination showed that each kit consisted of a leather case containing 1 first aid dressing, 6 iodine swabs, 1 18-gram tube of boric acid ointment, 1 2-oz. bottle of insect repellent, from 2 to 5 strip bandages, and 1 100-tablet bottle of halazone tablets.

Analysis showed that the tablets contained from 10 percent to 81 percent of the declared amount of halazone, whereas the National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 8–29–56, N. Dist. Ohio.

CHARGE: 501 (b)—the tablets purported to be and were represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and the strength of the tablets, while held for sale, differed from the standard set forth in such compendium.

DISPOSITION: 12–19–56. Consent—destruction.

5179. First aid kits. (F. D. C. No. 39418. S. No. 34–172 M.)

QUANTITY: 7 cases, each containing 32 *first aid kits* and each kit containing 1 btl. of halazone tablets, at Topeka, Kans.

SHIPPED: 2–21–56, from Tulsa, Okla.

LABEL IN PART: (Btl.) "100 Water Purification Tablets For Purifying Drinking Water in Canteens * * * Halazone N. N. R. (P-sulfonedichloramidobenzoic acid) Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium borate and chloride."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 3.8 percent to 92.3 percent of the declared amount of halazone.

LIBELED: 8–21–56, Dist. Kans.

CHARGE: 501 (b)—the strength of the article, while held for sale, differed from the standard for halazone tablets set forth in the National Formulary.

DISPOSITION: 11–30–56. Default—destruction.

5180. First aid kits. (F. D. C. No. 39488. S. No. 34–996 M.)

QUANTITY: 45 *first aid kits*, each containing 1 btl. of halazone tablets, at Berea, Ohio.

SHIPPED: 3–13–56, from New York, N. Y.

LABEL IN PART: (Btl.) "100 Water Purification Tablets * * * Halazone * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium borate and chloride."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 56 percent to 89 percent of the declared amount of halazone. The National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 10–1–56, N. Dist. Ohio.

CHARGE: 501 (b)—the strength and quality of the tablets, while held for sale, differed from the standard set forth in the National Formulary for halazone tablets.

DISPOSITION: 10–23–56. Default—destruction.

5181. Clinical thermometers. (F. D. C. No. 39274. S. No. 23–988 M.)

QUANTITY: 1,350 *clinical thermometers* at Long Beach, Calif.

SHIPPED: 3–30–56, from New York, N. Y., by Philbern Thermometer Co., Inc.

LABEL IN PART: (Ctn.) "One Fever Thermometer * * * Philbern."

ACCOMPANYING LABELING: Leaflet designated "Certificate of Examination Clinical Thermometer."

RESULTS OF INVESTIGATION: Examination revealed that 7 out of 24 thermometers taken from this lot failed to comply with the requirement for accuracy, 2 of which failed also to comply with the test for retreating index, specified in Commercial Standard CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in such standard.

LIBELED: 6–8–56, S. Dist. Calif.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statement in the labeling accompanying the article, namely, "This clinical thermometer has been tested by a Standard Thermometer, approved by the Bureau of Standards, Washington, D. C., at the following degrees and found to stand at: 98° 100° 104° 106°," was false and misleading.

DISPOSITION: 7–17–56. Consent—claimed by Philbern Thermometer Co., Inc. Segregated; 169 destroyed.

5182. Clinical thermometers. (F. D. C. No. 39246. S. No. 49–267 M.)

QUANTITY: 186 *clinical thermometers* at Chicago, Ill.

SHIPPED: 3–17–56, from New York, N. Y., by Philbern Thermometer Co., Inc.

LABEL IN PART: (Ctn.) "One Fever Thermometer * * * Philbern Rectal."

ACCOMPANYING LABELING: Leaflet designated "Certificate of Examination Clinical Thermometer."

RESULTS OF INVESTIGATION: Examination revealed that 3 out of 23 thermometers taken from this lot failed to comply with the requirement for accuracy specified in Commercial Standard CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in such standard.

LIBELED: 5–21–56, N. Dist. Ill.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statement in the labeling accompanying the article, namely, "This clinical thermometer has been tested by a Standard Thermometer, approved by the Bureau of Standards, Washington, D. C., at the following degrees and found to stand at: 98° 100° 104° 106°," was false and misleading.

DISPOSITION: 6–20–56. Default—destruction.

5183. Clinical thermometers. (F. D. C. No. 39290. S. Nos. 31–078/9 M.)

QUANTITY: 552 *clinical thermometers* (408 oral and 144 rectal) at Lancaster, Ohio.

SHIPPED: From Brooklyn, N. Y., by Hygrade Thermometer Co. (The date of shipment is unknown.)

LABEL IN PART: (Ctn.) "Clinical Thermometers Type—Oral (or Rectal) Tri-Top."

ACCOMPANYING LABELING: Leaflet designated "Certificate for DEBS Clinical Thermometers."

RESULTS OF INVESTIGATION: Examination revealed that 5 out of 24 oral and 11 out of 24 rectal thermometers failed to comply with the requirement for accuracy specified in Commercial Standard CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in such standard.

LIBELED: 6–29–56, S. Dist. Ohio.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statement in the labeling accompanying the article, namely, "This Certifies that these thermometers have been carefully compared with a standard thermometer, bearing certification mark of the U. S. Bureau of Standards * * * The manufacturers * * * guarantee that these thermometers have been tested and found to comply with the requirements of the Department of Commerce Commercial Standard CS1–52," was false and misleading.

DISPOSITION: 9–7–56. Default—destruction.

5184. Clinical thermometers. (F. D. C. No. 39245. S. Nos. 49–294/5 M.)

QUANTITY: 240 *clinical thermometers* (124 rectal and 116 oral) at Detroit, Mich.

SHIPPED: 4–17–56, from Brooklyn, N. Y., by Hygrade Thermometer Co.

LABEL IN PART: (Ctn.) "One Fever Thermometer * * * Kind Rectal (or Oral)."

ACCOMPANYING LABELING: Insert designated "Certificate for Clinical Thermometer."

RESULTS OF INVESTIGATION: Examination revealed that 11 out of 20 rectal thermometers and 22 out of 28 oral thermometers taken from the above shipment failed to comply with the requirement for accuracy specified in Commercial Standard CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in such standard.

LIBELED: 5–23–56, E. Dist. Mich.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the following statements in the labeling of the article, when shipped, were false and misleading since they were contrary to fact, namely, (ctn.) "Certification This thermometer has been made according to the regulations, and compared with standard thermometers. Verified by The U. S. Bureau Of Standards" and (leaflet) "Certificate For Clinical Thermometers Identification Number * * * Date * * * This Thermometer bearing the above trade mark and serial number has been carefully tested and compared, on above date, with our standard thermometer (certified by the United States Bureau of Standards)."

DISPOSITION: 7–16–56. Default—destruction.

5185. Clinical thermometers. (F. D. C. No. 39421. S. No. 52–761 M.)

QUANTITY: 288 *clinical thermometers* at Brooklyn, N. Y.

SHIPPED: 6–28–56, from Fort Smith, Ark., by Fort Smith Surgical Supply Co.

LABEL IN PART: (On thermometer) "Hygrade Oral"; (box) "3 Dozen Hospital Pack Brand Clinical Thermometers Type: Oral."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 4 thermometers failed to comply with the requirement for accuracy specified in Commercial Standard CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in such standard.

LIBELED: 10–31–56, E. Dist. N. Y.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the following statements in the labeling of the article were false and misleading since they were contrary to fact, namely, (insert in each box) "This Certifies that the enclosed thermometers have been tested on the above date and are correct. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1–52 Department of Commerce)."

DISPOSITION: 12–4–56. Default—destruction.

5186. Clinical thermometers. (F. D. C. No. 39032. S. No. 25–386 M.)

QUANTITY: 120 *clinical thermometers* at Seattle, Wash.

SHIPPED: 3–2–56, from Brooklyn, N. Y., by Cardinal Thermometer Co.

LABEL IN PART: (Ctn.) "Cardinal Fever Thermometer Kind—Oral."

ACCOMPANYING LABELING: (Leaflet in ctn.) "Certificate of Accuracy For Clinical Thermometer."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 9 failed to comply with Commercial Standard CS1–52 since 8 failed to give

readings of required accuracy and one failed to comply with the test for retreating index.

LIBELED: On or about 4–13–56, W. Dist. Wash.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported or was represented to possess; and Section 502 (a)—the following statements appearing in the accompanying labeling of the article were false and misleading since they were contrary to fact, namely, "* * * We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce * * *."

DISPOSITION: 6–25–56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5187. Alpha tablets and Mino tablets. (F. D. C. No. 38874. S. Nos. 38–824/5 M.)

QUANTITY: 475 100-tablet btls., 169 300-tablet btls., and 9 600-tablet btls. of *Alpha tablets*, and 147 100-tablet btls. and 18 250-tablet btls. of *Mino tablets*, at Homestead, Fla.

SHIPPED: 10–28–55, from Detroit, Mich., by Wolverine Laboratories, Inc.

LABEL IN PART: (Btl.) "Pain Relieving Alpha Tablets * * * Each Tablet Contains: Inert Ingredients: calcium gluconate and calcium lactate. Active Ingredient: aspirin. Base: Powdered extract of Alfalfa" and "Mino Tablets * * * Each Tablet Contains Thiamine HCl .50 mg., Riboflavin 1.00 mg., Niacin .30 mg., Pyridoxine HCl .01 mg., Calcium Pantothenate .20 mg., Vitamin D 1000 USP Units, Tryptophane 55 mg., Cystine .70 mg., Histidine 1.50 mg., Methionine 2.00 mg., Isoleucine 2.50 mg., Arginine 3.00 mg., Phenylalanine 3.00 mg., Tyrosine 3.00 mg., Threonine 3.00 mg., Valine 3.50 mg., Lysine 4.00 mg., Leucine 9.00 mg."

ACCOMPANYING LABELING: Display discs entitled "Alpha Tablets For Arthritis" and "Sinus! Headaches! Pain! Drainage! * * * Mino Tablets"; display cards entitled "Alpha Tablets For Rheumatism On Sale Here!" and "Mino Tablets For Sinus Infections"; display sheets entitled "Alpha Tablets For Arthritis"; streamers entitled "Alpha Tablets For Rheumatism On Sale Here," "Alpha Tablets For Arthritis," "Sinus! Try New Mino Tablets," and "Mino Tablets For Sinus On Sale Here"; insert sheets entitled "Alpha Tablets are Profit-Makers—*For You!* Because They Move"; newspaper mats entitled "A New Tablet For Arthritis containing Alfalfa * * * Alpha Tablets," "Alfalfa For Arthritis," and "Try New Mino Tablets for Sinus Sufferers"; leaflets entitled "Alpha Tablets For the Relief of Arthritis and Rheumatic Pain" and "Advertising Program Alpha Tablets For Arthritis Mino Tablets For Sinus."

LIBELED: 12–27–55, S. Dist. Fla.

CHARGE: 502 (a)—the labeling of the articles, when shipped, contained false and misleading statements that the *Alpha tablets* were an adequate and effective treatment for arthritis, rheumatism, neuritis, and neuralgia, and that the *Mino tablets* were an adequate and effective treatment for sinus infections and headaches and for preventing colds.

*See also Nos. 5163, 5166–5169, 5171, 5172, 5174, 5175, 5181–5186.

DISPOSITION: 5–7–56. Default—destruction.

5188. Beta-Sal tablets. (F. D. C. No. 39440. S. Nos. 52–226/7 M.)

QUANTITY: 2 29,000-tablet drums, 1 35,000-tablet drum, 1 16,000-tablet drum, and 425 50-tablet btls. at Bayonne, N. J., in possession of Todd-Dickson Pharmaceuticals, Inc.

SHIPPED: Between 3–16–55 and 6–5–56, from Brooklyn, Floral Park, and Rensselaer, N. Y.

LABEL IN PART: (Btl.) "50 Tablets Beta-Sal * * * Each Beta-Sal tablet contains Salicylamide 3.5 gr., Acetyl Salicylic Acid 5 gr., Magnesium Carbonate 1 gr., Ascorbic Acid 10 mg., Vitamin D 500 U. S. P. Units * * * Sole Owner and Distributor Todd-Dickson Pharmaceuticals New York City."

ACCOMPANYING LABELING: 5,800 Beta-Sal bottle labels, 1,098 Beta-Sal display cartons, and 860 display placards designated "Arthritis and Rheumatism."

RESULTS OF INVESTIGATION: The article was shipped in interstate commerce in bulk drums; and, upon receipt by the consignee, it was repackaged into bottles labeled as described above.

LIBELED: On or about 9–4–56, Dist. N. J.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was a new wonder drug; that the article would cause all sufferers of arthritis and rheumatism to feel good again; that it was an adequate and effective treatment for all types of arthritis, rheumatism, sciatica, bursitis, and lumbago; that it would give complete relief from all pain to all persons suffering from arthritis, rheumatism, sciatica, bursitis, and lumbago, even to those who had failed to find relief by any other means; that it would relieve all torturous pain in muscles and joints, regardless of cause; and that it would give complete relief from pain from morning to night to all persons suffering from any form of arthritis, rheumatism, sciatica, bursitis, and lumbago; and 502 (e) (2)—the label of the article, when shipped and while held for sale, failed to bear the common or usual name of each active ingredient contained in the article since the label of the 35,000-tablet drum and the 16,000-tablet drum bore no statement of the active ingredients and since the label of the 29,000-tablet drums and the 50-tablet bottles declared the active ingredient, aspirin, by the name of acetylsalicylic acid and not by its common and usual name.

DISPOSITION: 10–9–56. Default—destruction.

5189. Methylene blue compound. (F. D. C. No. 39684. S. No. 27–050 M.)

QUANTITY: 1 24,900-pill drum; 1 2,900-pill drum; and 40 ctns., 1 50-pill vial each, at New Orleans, La., in possession of Testo Products.

SHIPPED: Between 1947 and 1952, from Detroit, Mich.

LABEL IN PART: (Drum) "25,000 S. C. P. No. 1055 Methylene Blue Compound S. C. Pills (Blue) Methylene Blue—1 grain"; (ctn.) "Testo Pills * * * made from the purest ingredients * * * guaranteed not to contain any opiates or other habit-forming drugs."

ACCOMPANYING LABELING: Circular stating "Testo * * * Diuretic Pills A Stimulant Diuretic to the Kidneys * * * Methylene Blue, Cubeb, 1 gr. ea. Ext. Kava, Copaiba Mass, 1–4 gr. ea.; Oil Santal, 1–8 gr. Oil Nutmeg, Q. S."

RESULTS OF INVESTIGATION: Analysis showed the drug to be blue-colored, lime-coated, spherical tablets containing methylene blue, cubeb, oils, and resins.

The drug had been shipped in bulk, and the cartoned pills represented pills repacked and relabeled by the consignee.

LIBELED: 11–13–56, E. Dist. La.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for producing diuresis and overcoming internal pain in the region of the kidneys.

DISPOSITION: 12–26–56. Default—destruction.

5190. Rabro tablets. (F. D. C. No. 38994. S. No. 36–763 M.)

QUANTITY: 5,000 10-tablet unlabeled vials at Brooklyn, N. Y., in possession of Hugo Osthold, Inc.

SHIPPED: 10–20–55, in bulk, from Nijmegen, Holland.

LABEL IN PART: (Box) "Liquorice Bismuth Therapy Rabro * * * Formula: Succus Liquiritae 300 mg. Bismuthi Subnitras 350 mg. Magnesii Carbonas Levis 400 mg. Sodii Bicarbonas 200 mg. Frangula 25 mg. Calamus 25 mg. Made in Holland Packaged And Labeled In U. S. A. Hugo Osthold, Inc. Sole Distributors In the U. S. A."

ACCOMPANYING LABELING: Leaflet designated "Rabro Stomach Tablets * * * Directions for use."

RESULTS OF INVESTIGATION: The consignee intended to repack the drug into boxes labeled as described above, each box containing 5 unlabeled 10-tablet vials, together with the above leaflet.

LIBELED: 3–21–56, E. Dist. N. Y.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for gastritis and gastric and duodenal ulcers; 502 (b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; and 502 (e) (2)—the article was a drug fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient contained in the drug.

DISPOSITION: 9–25–56. Default—destruction.

5191. C-Tone. (F. D. C. No. 39239. S. No. 25–417 M.)

QUANTITY: 5 cases, 12 8-oz. btls. each, at Seattle, Wash.

SHIPPED: 2–8–56, from Englewood, N. J., by Kegan Research Laboratory, Inc.

LABEL IN PART: (Btl.) "Natural Vitamin C A palatable high-potency aqueous extract derived solely from botanical sources. For the correction of conditions caused by deficiency of Vitamin C. C-Tone 4 tablespoons provide Natural Vitamin C . . . 250 mg. (8 times the minimum daily adult requirement) also the following naturally occurring factors: Vitamin K 1 mg., Niacin .08 mg., Rutin (Vitamin P Complex) 5 mg., Pectin (Protopectins incl.) 500 mg., Citric Acid 57 mg., and nutritionally unimportant amounts of Vitamin B_1 and B_2, Calcium and Phosphorus. Prepared by a special process from the fruit and

foliage of the Persian walnut tree, in a palatable syrup base of dextrose and water."

ACCOMPANYING LABELING: Leaflets entitled "C-Tone New C-Tone direct from nature's laboratory."

LIBELED: 5–17–56, W. Dist. Wash.

CHARGE: 502 (a)—The labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective to strengthen the heart, sharpen memory, correct high blood pressure, reduce weight, overcome tiredness and nervousness, insure health and vitality in the aged, and rejuvenate the body.

DISPOSITION: 8–13–56. Default—destruction.

5192. True Tone tonic. (F. D. C. No. 39474. S. No. 44–908 M.)

QUANTITY: 12 8-oz. btls. at Washington, D. C.

SHIPPED: 3–20–56, from Savannah, Ga., by General Products Co.

LABEL IN PART: "Purcell's True Tone The South's Favorite Tonic * * * Active Ingredients: Solution Iron Chloride, USP * * * Acid, USP * * * Epsom Salts, USP (Magnesium Sulphate USP) Color added."

ACCOMPANYING LABELING: Leaflets entitled "The Old Reliable True Tone Tonic."

LIBELED: 9–18–56, Dist. of Columbia.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for high blood pressure, rheumatism, indigestion, constipation, gas on stomach, dizziness, kidney disorders, stomach disorders, weak back, aches and pains, weak rundown condition, and nervousness.

DISPOSITION: 10–19–56. Default—destruction.

5193. Lexino herb tonic and Lexino cough medicine. (F. D. C. No. 38950. S. Nos. 31–915/16 M.)

QUANTITY: 70 1-pt. btls. of *Lexino herb tonic* and 10 cartoned 8-oz. btls. of *Lexino cough medicine* at Wilkes-Barre, Pa.

SHIPPED: 1–3–56, from Lisbon, Conn., by General Products Corp.

LABEL IN PART: (Btl.) "Lexino Herb Tonic Alcohol 1% Active Ingredients: Aloin, Cascara, Gentian, Wild Cherry, Rhubarb, Broom Tops, Senna, Senna Pods, Centaury, Bitter Orange Peel, Uva Ursi, Golden Seal Herb, Triticum, Peppermint Buchu, Licorice, Sarsaparilla, Cardamon, Cinnamon, Caraway. Diuretic * * * Laxative * * * Stomachic * * * Carminative" and "Lexino * * * Cough Medicine Active Ingredients: Senega, Thyme, Squills, Senna, Capsicum, Anis, Ammonium Chloride, Ammonium Carbonate, Sodium Citrate, and Menthol. It gives quick relief in the treatment of coughs due to colds, Bronchial Irritations, and Catarrhal conditions and Irritations of the throat."

ACCOMPANYING LABELING: Leaflet entitled "Truly Helpful Medicines."

LIBELED: 2–13–56, M. Dist. Pa.

CHARGE: 502 (a)—the labeling of the articles, when shipped, contained the following false and misleading representations:

1. That the *Lexino herb tonic* was a tonic and was suitable for frequent and continuous use; that it was effective to tone up the organs of the body and aid them in throwing off impurities and dangerous wastes; that it was an effective

treatment for those who lack pep and ambition, tire easily, feel irritable at the slightest provocation, and become pale and nervous; that it was effective to make one feel better and look better; and that it was effective as a useful remedy for those who were ailing from whatever cause.

2. That the *Lexino cough medicine* was an adequate and effective treatment for bronchial irritations and catarrhal conditions; that it was effective as a tonic; that it was effective to tone up the organs of the body and aid them in throwing off impurities and dangerous wastes; that it was an effective treatment for those who lack pep and ambition, tire easily, feel irritable at the slightest provocation, and become pale and nervous; that it was effective to make one feel better and look better; and that it was effective as a useful remedy for those who were ailing from whatever cause.

DISPOSITION: 5–11–56. Default—destruction.

5194. Herb tea. (F. D. C. No. 39301. S. No. 48–838 M.)

QUANTITY: 85 lbs. bulk, 54 4-oz. repackaged ctns., and 1,900 empty ctns. at Green Bay, Wis., in possession of Wm. Horner Co.

SHIPPED: 3–27–56, from Jersey City, N. J.

LABEL IN PART: (Bag) "55229 173 52½ 2½ 30 Cut and Sifted Mixed Herb Tea Formula #67 Containing the following: TV Senna Leaves, Uva Ursi Leaves, Cascara Sagrada, Spanish Anise Seed, Licorice Root, Fennel Seed, Elder Flowers, Dandelion Root Caution—For manufacturing processing or repacking * * * Wm. Horner Co. Green Bay, Wis."; (ctn.) "Horner's Herb Tea * * * Made from roots, barks and leaves."

LIBELED: 7–13–56; amended 8–7–56, E. Dist. Wis.

CHARGE: 502 (a)—the label of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for bowel trouble, stomach trouble, kidney trouble, bladder trouble, pimples, indigestion, and tired feeling.

DISPOSITION: 11–1–56. Default—destruction.

5195. Cider vinegar. (F. D. C. No. 37559. S. No. 9–208 M.)

QUANTITY: 59 cases, 24 16-oz. btls. each, at Los Angeles, Calif.

SHIPPED: 11–26–54, from New York, N. Y., by Sterling Cider Co., Inc.

LABEL IN PART: (Btl.) "Full Strength Cider Vinegar * * * For Medicinal Use."

ACCOMPANYING LABELING: Brochures entitled "Saving Lives With Vinegar" and leaflets entitled "Sterling Cider Vinegar."

LIBELED: 12–29–54, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for chronic bronchitis, bronchiectasis, and chronic pulmonary suppuration, and for taking off excess weight.

DISPOSITION: 1–21–57. Default—destruction.

5196. A–1 salve. (F. D. C. No. 39422. S. No. 30–847 M.)

QUANTITY: 40 ctns., each containing 1 2-oz. or 4-oz. jar, at Louisville, Ky.

SHIPPED: During 1955 and January 1956, from Chicago, Ill.

LABEL IN PART: (Jar) "A–1 Salve * * * Active Ingredients: Salicyclic Acid Sulphur Zinc Oxide In a base of: Lanolin & Petrolatum."

ACCOMPANYING LABELING: Placards entitled "Skin Disorders or Mycotic Infections?"

LIBELED: 8–22–56, W. Dist. Ky.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for skin disorders, varicose ulcers, weeping eczema, psoriasis, alopecia, and eczema.

DISPOSITION: 11–8–56. Default—destruction.

5197. Triangular bandage. (F. D. C. No. 39035. S. No. 40–091 M.)

QUANTITY: 49 ctns., each containing 10 pkgs., at Chicago, Ill.

SHIPPED: 1–26–56, from Worcester, Mass., by Handy Pad Supply Co.

LABEL IN PART: (Pkg.) "40 Inch Triangular Bandage Sterilized Wm. V. MacGill & Co. * * * Can also be used as a sterile compress in the absence of a compress bandage."

LIBELED: 4–17–56, N. Dist. Ill.

CHARGE: 502 (a)—the label statements "Sterilized" and "Can also be used as a sterile compress in the absence of a compress bandage" were false and misleading as applied to the article, which was not sterile.

DISPOSITION: 10–25–56. Default—destruction.

DRUGS FOR VETERINARY USE

5198. Blake's Mineral Compound. (Inj. No. 282.)

COMPLAINT FOR INJUNCTION FILED: 2–9–55, Dist. Colo., against Harvey H. Rosenbaum, t/a Hy-Life Mineral Co., Denver, Colo.; Dencolo Corp., Denver, Colo.; and Christy Mathews, president of the corporation, to enjoin the interstate shipment of the above-mentioned drug, which was misbranded.

ACCOMPANYING LABELING: Circular entitled "For Sheep and Cattle pasturing in green alfalfa and clover meadows feed Blake's Mineral Compound."

RESULTS OF INVESTIGATION: The drug was a red powder which was shipped in 105-lb. bags and 3½-lb. cartons. The main ingredients were ammonium chloride, potassium chlorate, sodium sulfate, calcium carbonate, and tobacco powder. The drug contained also iron oxide and oil of anise.

CHARGE: The complaint charged that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of the drug, which was misbranded as follows:

502 (a)—the carton label and the accompanying circular contained false and misleading representations that the article was effective for treating and preventing bloat and the effects of poison weeds in sheep and cattle;

502 (a)—the name "Blake's Mineral Compound," the representation that the declared ingredients were active, and the directions for use appearing on the label of the article were false and misleading in that such name and representation suggested that the article furnished essential minerals required by sheep and cattle; whereas, ammonium chloride and sodium sulfate are not required by sheep and cattle, tobacco powder is not a mineral, and when used as directed, the article furnished inconsequential nutritional amounts of potassium chlorate and calcium carbonate.

The complaint alleged also that if the defendants were forced by an injunction to refrain from using the above-mentioned accompanying labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article

in interstate commerce without labeling stating the conditions and purposes for which the article was intended; and that, in such case, the article would be misbranded under 502 (f) (1), in that its labeling would fail to bear adequate directions for use because of the omission from such labeling of statements of the conditions and purposes for which the article was intended.

The complaint alleged further that the defendants were well aware that their activities were violative of the Act; that 10 seizures had been made of the article since 1945, 2 of which were contested; and that 3 notices of hearing were issued during 1946 and 1947, based on essentially the same charges of misbranding under 502 (a) as alleged in the complaint.

DISPOSITION: On 7–15–55, with the consent of the defendants, a preliminary injunction was entered. On 6–14–56, the defendants having consented, a decree of permanent injunction was entered enjoining the defendants from causing the introduction and delivery for introduction into interstate commerce of *Blake's Mineral Compound* or any other drug of similar composition which is misbranded as follows:

(a) under 502 (a) by reason of any representation or suggestion in the labeling of such article that the article is effective for treating and preventing bloat or the effects of poison weeds in sheep and cattle, or by reason of any other false or misleading representation or suggestion in the labeling of the article;

(b) under 502 (a) by reason of any representation which suggests or implies that the article furnishes essential minerals required by sheep and cattle; or

(c) under 502 (f) (1) because the labeling of such article fails to state all the conditions and purposes for which the article is intended.

5199. Piperate tablets and powder. (F. D. C. No. 39077. S. Nos. 51–541 M, 51–553/5 M, 51–577 M, 51–579/80 M.)

QUANTITY: 25 100-tablet btls., 3 1,000-tablet btls., 19 4-oz. btls., and 20 1-lb. btls. at Denver, Colo.

SHIPPED: Between 11–29–55 and 4–30–56, from Fort Dodge, Iowa, by Fort Dodge Laboratories, Inc.

LABEL IN PART: (Btl.) "Fort Dodge * * * Piperate Tablets * * * Each tablet contains: Piperazine Adipate . . . 250 mg." and "Fort Dodge Piperate Piperazine Adipate Active ingredient: Piperazine Adipate, 100%."

LIBELED: 5–24–56, Dist. Colo.

CHARGE: 502 (a)—the statement on the label of the article (tablets), when shipped, "Indications: For removal of * * * hookworms (Uncinaria stenocephala) in dogs" was false and misleading since the article was not effective for the removal of hookworms infesting dogs in this country; and the label of the article (powder), when shipped, contained statements which represented and suggested that the article was an adequate and effective treatment for nodular worms in horses and pinworms and strongyles in swine, cattle, and poultry, which statements were false and misleading since these animals are not subject to such conditions.

DISPOSITION: 9–24–56. Consent—claimed by Fort Dodge Laboratories, Inc., and relabeled.

5200. Pratts In-Tes-Trol. (F. D. C. No. 38990. S. No. 43–953 M.)

QUANTITY: 9 100-lb. drums at Springdale, Ark.

SHIPPED: 3–1–56, from Hammond, Ind., by Pratt Food Co., Inc.

LABEL IN PART: (Drum) "Pratts In-Tes-Trol (Powder) * * * For Chickens And Turkeys Of All Ages Active Ingredients: Methylrosanline (Gentian Violet) Copper Sulfate (Hydrated) 40% Ferrous Sulfate (Copperas) Zinc Sulfate, Manganese Sulfate, Tartaric Acid Inert Calcium Sulfate (Nature) 50%."

ACCOMPANYING LABELING: (Leaflet enclosed in each drum) "Pratts In-Tes-Trol (Powder) For Chickens And Turkeys Of All Ages."

LIBELED: 3–30–56, W. Dist. Ark.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for overcoming and preventing mycosis in poultry.

DISPOSITION: 5–19–56. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5161 TO 5200

PRODUCTS

[1] (5198) Injunction issued.
[2] (5163) Seizure contested. Contains opinion of appellate court and decree of condemnation of district court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5198) Injunction issued.
[2] (5163) Seizure contested. Contains opinion of appellate court and decree of condemnation of district court.

U. S. GOVERNMENT PRINTING OFFICE: 1958

The Federal Register publishes the full text of Presidential Proclamations and Executive Orders, and the rules and regulations of the various Departments of the Federal Government.

D. D. N. J., F. D. C. 5201–5220 Issued July 1958

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5201–5220

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They relate to drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) criminal proceedings which were terminated with a plea or verdict of guilty; (3) injunction proceedings terminated with the entry of an injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 25, 1958.*

CONTENTS *

*For omission of, or unsatisfactory, ingredients statements, see Nos. 5201, 5217; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5201; cosmetic, actionable under the drug provisions of the Act, No. 5217.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS 5201–5220

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5201. R–20 hair treatment. (F. D. C. No. 39640. S. No. 40–913 M.)

QUANTITY: 2 btls., containing 20 oz. total, of *R-20 hair treatment*, and 2 jugs, 1 containing 1 gal. and the other containing 28 oz., of diluted *R-20 hair treatment*, at Minneapolis, Minn.

SHIPPED: 8-23-56, from Rouses Point, N. Y., by Dr. R. E. Liefmann.

LABEL IN PART: (Btl.) "R-20 Batch #17, 8–27–56 Regular"; (jug) "the Frommes formula R-20 by Frommes Scalp Specialists Minneapolis."

RESULTS OF INVESTIGATION: Analysis showed that the drug consisted of an isopropyl alcohol solution of alpha-estradiol. The drug was shipped unlabeled, and, upon arrival, the handwritten bottle labeled "R-20 Batch #17 8–27–56 Regular" was affixed by the consignee, Frommes Method, Inc.

The diluted material was prepared by the consignee by adding an additional quantity of isopropyl alcohol to a portion of the shipped drug. The "Frommes formula R-20" labels were printed locally for the consignee, who applied them to the diluted material.

LIBELED: 10–24–56, Dist. Minn.

CHARGE: 502 (b) (1)—the label of the article, when shipped, failed to bear the name and place of business of the manufacturer, packer, or distributor; 502 (e) (2)—the article was fabricated from 2 or more ingredients, and its label, when shipped, failed to bear the common or usual name of each active ingredient; 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use; and 503 (b) (4)—the article was a drug which was not safe for use except under the supervision of a practitioner li-

censed by law to administer such drug, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12–14–56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5202. Hoxsey treatment for internal cancer. (Inj. No. 311.) *See also* N. J. No. 5212 in this supplement.

COMPLAINT FOR INJUNCTION FILED: 5–28–57, W. Dist. Pa., against Hoxsey Cancer Clinic, a corporation, Portage, Pa., John J. Haluska, president and administrator, Philip Stager, treasurer, Samuel Einhorn, secretary, John H. Benko, vice president, and Delmar Randall and Harold Galbraith, osteopathic physicians employed by the corporation.

An amended complaint was filed on 8–22–57.

ACCOMPANYING LABELING: Booklet entitled "What is Cancer? How Does It Function?"; pamphlet entitled "Procedure and Information, Hoxsey Cancer Clinic, Inc."; miscellaneous reprints of articles and letters written and distributed by John J. Haluska; monthly publication entitled "Globe Gazette"; and book entitled "The Pittsburgh Trial."

NATURE OF DRUGS: The original complaint alleged that the essential part of the *Hoxsey treatment for internal cancer* was either a combination of green and red tablets or a combination of yellow and red tablets.

The complaint alleged also that the green tablets were composed of licorice, burdock root, stillingia root, berberis root, pokeroot, cascara sagrada, prickly ash bark, buckthorn bark, and red clover; that the yellow tablets were composed of red clover, buckthorn bark, stillingia root, berberis root, pokeroot, and pepsin; and that the red tablets were composed of potassium iodide.

The complaint alleged further that at times the potassium iodide was furnished as a liquid solution or omitted entirely.

METHOD OF OPERATION: The original complaint alleged that a typical method used by the defendants in the promotion, sale, and distribution of the treatment, in interstate commerce, was as follows: Interest in the treatment was promoted by articles appearing in the Globe Gazette, edited by John J. Haluska, and by articles published in the Defender magazine, edited by Gerald B. Winrod. In response to an inquiry concerning the treatment, from a person living outside Pennsylvania, an invitation to visit the clinic was issued in a letter bearing the facsimile signature of defendant Harold L. Galbraith as medical director of the clinic. When the prospective out-of-state customer arrived on the premises of the clinic, he was interviewed by the employees, at which time there was a discussion of his symptoms and ailments. This was followed by laboratory tests of the blood and urine, X-rays, and a physical examination of the customer. On that basis, the prospective customer's condition was diagnosed as cancer without a biopsy. The customer then was sold the *Hoxsey treatment for internal cancer*, comprised essentially of the above-described tablets, and the treatment was delivered to the customer for transportation outside Pennsylvania.

On 8–22–57, the complaint was amended to include the allegation that, upon entry of the temporary restraining order as described below, the defendants did the following: With no notice to the persons going to the

*See also No. 5201.

clinic for the Hoxsey treatment, and without changing the labeling representations and suggestions that they were distributing the *Hoxsey treatment for internal cancer* in man, the defendants discontinued the delivery of the above-described combinations of pills, which were, as the defendants had admitted, the essential part of the *Hoxsey treatment for internal cancer* in man. In substitution, the defendants delivered to people going to the clinic from outside Pennsylvania a group of simple medications— usually brewer's yeast tablets, ascorbic acid (vitamin C) tablets, antacid tablets, laxative tablets, and pain pills—previously given as supportive treatment for the cancer medicines; and, in lieu of the above combinations of tablets, the clinic gave a prescription for a saturated solution of potassium iodide, to be filled by an outside pharmacy.

CHARGE: The original complaint alleged that the defendants were engaged in promoting, selling, distributing, and causing to be introduced and delivered for introduction into interstate commerce the so-called *Hoxsey treatment for internal cancer*, the essential part of which consisted of the combination of green and red tablets or the combination of yellow and red tablets. It was alleged also that when the tablets were caused to be introduced and delivered into interstate commerce, the tablets were misbranded as follows:

502 (a)—the tablets were accompanied by the above labeling, which falsely represented and suggested that the *Hoxsey treatment for internal cancer* was an adequate and effective treatment for internal cancer in man;

502 (f) (1)—at times, no labeling accompanied the tablets, in which case the labeling of the tablets failed to bear adequate directions for use in that their labeling failed to state that the tablets were intended for the treatment of cancer;

502 (f) (1)—with or without the above labeling, the tablets failed to bear labeling stating adequate directions for use in that the directions as to dosage and frequency and duration of administration were not adequate for the treatment for which the tablets were intended, namely, cancer, since the tablets were worthless for the treatment of cancer and adequate directions could not be given for the use of the above-described tablets in the treatment of cancer.

The original complaint alleged also that the *Hoxsey treatment for internal cancer* had been adjudged worthless for the treatment of cancer in man on two previous occasions resulting in: (a) a decree of permanent injunction, dated 10–26–53, issued by the United States District Court for the Northern District of Texas (see D. D. N. J. No. 4654) and (b) a decree of condemnation, pursuant to a jury verdict rendered on 11–16–56, in the United States District Court for the Western District of Pennsylvania (see D. D. N. J. No. 5212); that the defendants were in privity with the persons bound by the two judgments and were themselves bound by them and precluded by the two judgments from denying that the Hoxsey treatment was inadequate and ineffective in the treatment of internal cancer in man; that the corporate defendant was the successor to the Hoxsey Cancer Clinic, claimant in the seizure case, which the individual defendants, Haluska, Stager, Einhorn, and Benko, together with Newton C. Allen, operated from the time it opened until it was succeeded by the corporation; that the individual defendants were financially interested in the clinic and obtained profits from it; and, therefore, the defendants were aware and bound by the above judgments and knew their activities were violative of the Act.

The amended complaint charged that the defendants, after the entry of the temporary restraining order, caused to be introduced and delivered for introduction into interstate commerce the substitute drugs which were misbranded under 502 (a):

(1) in that the labeling represented and suggested that such drugs comprised the *Hoxsey treatment for internal cancer*, whereas the essential part of the treatment had been discontinued; and

(2) in that the labeling failed to state the material fact that the Hoxsey Cancer Clinic no longer distributed or delivered to out-of-state patients with cancer the tablets that comprised the essential part of the Hoxsey cancer treatment.

DISPOSITION: On 5-28-57, the court issued a temporary restraining order enjoining the defendants against the commission of the acts complained of. By agreement of the parties, the temporary restraining order was extended on 6-19-57 until trial on the issues. The defendants filed their answers to the complaint on 7-15-57.

A pretrial conference was held on 8-22-57, at which time the court entered an order amending the complaint to include the additional charges above. Also, the Government moved for inclusion of the testimony of certain witnesses who had testified in the above-mentioned seizure case in the trial on the issues in this case. It was the opinion of the court that an order from the United States Court of Appeals for the Third Circuit was necessary before the testimony could be so incorporated, inasmuch as the seizure case (see D. D. N. J. No. 5212) was being appealed to the court of appeals at that time.

Accordingly, the Government filed a motion in the United States Court of Appeals for the Third Circuit for an order to permit the United States District Court for the Western District of Pennsylvania to incorporate such testimony in the instant case. The motion was granted by the court of appeals on 9-4-57.

On 9-6-57, the district court entered the following order:

MEMORANDUM ORDER

GOURLEY, *Chief Judge:* "It appears in this proceeding after pre-trial conference that substantial dispute exists between the parties as to the legal effect of the adjudication of Civil Action No. 13251, which involved the same parties, and as to the intent of Judge Miller in his adjudication of the many matters that were presented to him that justice would be best served if the proceeding would be heard by the same judge who administered and adjudicated the trial of the companion proceeding.

NOW, THEREFORE, this 6th day of September, 1957, the within proceeding is assigned to the Honorable John L. Miller for trial on the 23rd day of September, 1957, and all matters relative thereto shall be presented to said member of the court for consideration, determination and adjudication."

The case came on for trial on 9-23-57. On 10-2-57, at the conclusion of the Government's case, the court entered the following consent decree of permanent injunction:

MILLER, *District Judge:* "The plaintiff's complaint praying for a permanent injunction having come on for hearing and the testimony of the plaintiff having been taken, the defendants indicated a desire to consent to the entry of a decree of permanent injunction in the manner and form prayed for by the plaintiff.

"IT IS THEREFORE ORDERED that the defendants, Hoxsey Cancer Clinic, Inc., a corporation, and John J. Haluska, Philip Stager, Samuel Ein-

horn, John H. Benko, Delmar Randall, and Harold Galbraith, individuals, and their officers, agents, servants, employees, representatives, and all other persons in active concert or participation with them or any of them, be and they are hereby perpetually enjoined and restrained from directly or indirectly, introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and more particularly delivering or causing to be delivered to any patient or customer living outside the Commonwealth of Pennsylvania for transportation in interstate commerce, in violation of Section 301 (a) of said Act (21 U. S. C. 331 (a)), the articles of drug known as the Hoxsey treatment for internal cancer, and any other articles of drug, the labeling of which represents or suggests that the said drugs comprise the Hoxsey treatment for internal cancer in man, and any other drug or similar composition which—

(a) are accompanied by the aforesaid labeling, namely, the booklet entitled, "What is Cancer? How Does it Function?" a pamphlet entitled, Procedure and Information. Hoxsey Cancer Clinic, Inc.," miscellaneous reprints of articles and letters written and distributed by John J. Haluska, a monthly publication entitled the "Globe Gazette," and a book entitled, "The Pittsburgh Trial," devoted substantially to the promotion of the Hoxsey treatment;
(b) are represented or suggested in their labeling to be adequate and effective in the treatment of cancer in man;
(c) are misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any false or misleading representations or suggestions in the labeling of such drugs;
(d) are misbranded within the meaning of Section 502 (f) (1) of the Act (21 U. S. C. 352 (f) (1)) by reason of the failure of the labeling of said articles to bear adequate directions for use because of the omission from said labeling of a statement of the condition or disease, namely, cancer, which said articles are intended to treat or prevent, and because the directions as to how to take the medicines are not adequate for the condition for which the said medicines are intended."

5203. Nutrilite food supplement. (F. D. C. No. 37261. S. Nos. 88–421 L, 88–430 L.)

INFORMATION FILED: 9–30–55, W. Dist. N. Y., against John Josef and Elinor M. F. Josef, Rochester, N. Y.

ALLEGED VIOLATION: In the course of a sales talk given at Rochester, N. Y., on 9–24–54, Elinor M. F. Josef made oral representations holding the article out to the persons present as an effective treatment for diabetes, cancer, multiple sclerosis, nervousness, arthritis, psoriasis, and malaria; and in the course of sales talks given at Rochester, N. Y., on 9–28–54, John Josef and Elinor M. F. Josef made additional oral representations holding the articles out to the persons present as an effective treatment for multiple sclerosis, diabetes, psoriasis, arthritis, muscular dystrophy, nervousness, paralysis, cerebral palsy, ulcerated stomach, neuritis, pyorrhea, high blood pressure, bad eyesight, alcoholism, nervous breakdown, rheumatism, heart trouble, amyotrophic lateral sclerosis, hypertension, facial flushes, headaches, dizziness, and a letdown feeling.

The acts of the defendants in making such oral representations resulted in the article being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Pkg.) "Nutrilite (R) XX [or "Junior"] Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions

for which it was intended, namely, the diseases, symptoms, and conditions set forth above.

PLEA: Not guilty.

DISPOSITION: On 11–25–55, the defendant filed a motion for a bill of particulars, and on 1–27–56, the court granted the motion with respect to 2 of the 6 items on which particulars were requested. Thereafter, the defendants filed a motion for dismissal of the information on the ground that it did not state sufficient facts to constitute an offense against the United States, and on 6–27–56, the court denied the motion.

The case came on for trial before the court and jury on 5–21–57, and was concluded with the return by the jury, on 5–24–57, of a verdict of guilty.

On 6–3–57, the court fined John Josef $500 and Elinor M. F. Josef $1,000, but remitted $500 of the latter fine.

5204. Keystone blood and kidney remedy. (F. D. C. No. 38506. S. Nos. 30–509 L, 64–764 L.)

INDICTMENT FILED: 9–12–56, W. Dist. Wash., against Forward Club, a corporation, Seattle, Wash., and James L. Evans, president.

ALLEGED VIOLATION: On 9–9–54, while a number of bottles of *Keystone blood and kidney remedy* was being held for sale on the premises of the Forward Club, after shipment in interstate commerce, the defendants caused the drug to be associated with various items of written, printed, and graphic matter relating to the sales promotion of the drug, which act resulted in the drug being misbranded.

LABEL IN PART: "Keystone Blood & Kidney Remedy Ingredients: Herbs And Organic Minerals."

CHARGE: 502 (a)—The labeling associated with the drug, while held for sale after shipment in interstate commerce, contained false and misleading representations that the drug was effective for the prevention and treatment of cancer, as well as for overcoming kidney ailments, chronic liver and gallbladder trouble, and diabetes, and for the prevention and treatment of liver trouble, ulcers, kidney trouble, colds, hemorrhoids, piles, diarrhea, rheumatism, dysentery, neuralgia, lung trouble, hemorrhages, and fever; and 502 (f) (1)—the labeling of the drug failed to bear adequate directions for use.

PLEA: Guilty.

DISPOSITION: 10–29–56. Forward Club fined $500; Evans fined $100 and placed on probation for 5 years.

5205. Various drugs. (F. D. C. No. 38725. S. Nos. 7–879/89 M.)

QUANTITY: 1 drum containing 24,750 *Special Formula Tablets Laxative No. 1;* 1 drum containing 9,750 and 1 drum containing 12,950 *KH thyroid tablets;* 1 drum containing 17,550 *KH #211 tablets;* 2 boxes containing a total of 7,250 *Special Formula No. 3044 tablets;* 1 jar containing 4,750 *Thyrotalis RP–2 tablets;* 3 jars containing a total of 12,450 *Private Formula capsules;* 4 drums, 12,500 tablets each, and 2 drums, containing a total of 57,750 tablets, of *KH #215 tablets;* 1 drum containing 19,500 *KH Special tablets;* and 3 drums containing a total of 31,500 *KH–RP 2 tablets,* at Oklahoma City, Okla., in possession of Kirk-Howard, Inc.

SHIPPED: Between 7–27–54 and 9–21–55, the article labeled "Special Formula Tablets Laxative No. 1" was shipped from Memphis, Tenn., by William A.

Webster Co. The other articles were shipped by other firms from Union City, N. J., St. Louis, Mo., and Dallas, Tex.

LABEL IN PART: (Drum) "Special Formula Tablets Laxative No. 1 Sugar Coated Blue Pil. Rhubarb Comp. 1 grain Ext. Cascara ½ grain Asafoetida ½ grain Aloin 1/16 grain Ext. Nux Vomica 1/10 grain (equivalent strychnine .0074 grain) Oleoresin Ginger 1/16 grain Oil Peppermint q. s. Lot No. 3253," "KH–2 gr. Thyroid Each Table Contains: Thyroid U. S. P. 2 gr. * * * Caution: Federal law prohibits dispensing without prescription," "KH #211 Each tablet contains: Thyroid U. S. P. 2 gr. Digitalis U. S. P. 1 gr. * * * Caution: Federal law prohibits dispensing without prescription," "KH #215 Each tablet contains: Thyroid U. S. P. 3 gr. Digitalis U. S. P. ¾ gr. * * * Caution: Federal law prohibits dispensing without prescription," "KH Special (formerly #35) Each tablet contains: Inert Ingredient 1½ gr. Thyroid U. S. P. 2 gr. * * * Caution: Federal law prohibits dispensing without prescription," or "KH–RP 2 Each tablet contains: Thyroid U. S. P. 1 gr. Digitalis U. S. P. ½ gr. * * * Caution: Federal law prohibits dispensing without prescription"; (box) "Special Formula No. 3044 * * * Each tablet contains yellow phenolphthalein, Not U. S. P. 2 gr. Bryonia 1/40 gr. Hydrastis 1/40 gr. An active laxative"; (jar) "Thyrotalis RP–2 Caution—Federal Law Prohibits Dispensing Without Prescription * * * Each tablet contains: Thyroid Disis. [sic] U. S. P. 1 gr. Digitalis Pwd. U. S. P. ½ gr.," or "Private Formula Capsules Thyrotalis RP–2 No. of Formula #7232 * * * Rx per capsule: Thyroid Disiccated [sic] U. S. P. 1 gr. Digitalis U. S. P. Powd. ½ gr. Milk Sugar 1 gr."

RESULTS OF INVESTIGATION: Kirk-Howard, Inc., did business in the residence of Peter W. Burgess, president of the corporation and partner in the Burgess Weight Control Clinic, which was located in the same residence. Part of the above articles were used in the Burgess Weight Control Clinic.

The drugs were dispensed without medical supervision and without the prescription of a practitioner licensed by law to administer them since neither Peter W. Burgess nor his assistant were licensed to administer or dispense drugs.

LIBELED: 12–6–55, W. Dist. Okla.

CHARGE: 502 (f) (1)—the articles were intended to be used in weight reduction, and their labelings failed to bear adequate directions for use for that purpose while held for sale; and 502 (f) (2)—the article labeled "Special Formula Tablets Laxative No. 1," when shipped, failed to warn against use of the article when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present; also, that frequent or continued use of the article might result in dependence on laxatives.

DISPOSITION: 1–9–56. Consent—claimed by Kirk-Howard, Inc. The articles were released on condition that the nonprescription drugs be relabeled and thereafter sold and that the prescription drugs be sold or otherwise disposed of to licensed drug stores, licensed prescription shops, or licensed physicians and surgeons.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5206. Sulfanilamide tablets. (F. D. C. No. 38526. S. No. 7–515 M.)

INDICTMENT RETURNED: 6–1–56, Dist. Colo., against Earl O. Meyer Drugs, Inc., Denver, Colo., and Earl O. Meyer, president.

ALLEGED VIOLATION: On 3-17-55, while a number of *sulfanilamide tablets* were being held for sale by the defendants after shipment in interstate commerce, the defendants caused to be dispensed, sold, and delivered to a customer a number of such tablets in place of the sulfaguanidine tablets called for by the prescription, which was presented by the customer to the defendants for filling.

CHARGE: 501 (d) (2)—Sulfanilamide had been substituted for sulfaguanidine.

PLEA: Guilty.

DISPOSITION: 10-26-56. Corporation fined $1,500; individual sentenced to 4 months in prison.

5207. Sodium ascorbate injection (vitamin C). (F. D. C. No. 39492. S. No. 26-364 M.)

QUANTITY: 1,051 ampuls at Minneapolis, Minn.

SHIPPED: 1-18-56 and 2-24-56, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: "2 cc. Vitamin C (Sod. Ascorbate) 500 Mg. p. cc."

RESULTS OF INVESTIGATION: Examination showed that some ampuls were not properly sealed and that part of the contents had leaked out. Assay of the sealed ampuls showed that they contained approximately 280 mg. of sodium ascorbate per cubic centimeter.

LIBELED: 10-1-56, Dist. Minn.

CHARGE: 501 (b)—The article purported to be "Sodium Ascorbate injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, the strength of the article differed from, and its quality fell below, the official standard; and 502 (a)—the ampul label statement set forth above was false and misleading as applied to a product containing less than 500 mg. of sodium ascorbate per cubic centimeter.

DISPOSITION: 11-26-56. Default—destruction.

5208. Halazone tablets. (F. D. C. No. 39420. S. No. 34-033 M.)

QUANTITY: 600 100-tablet btls.; 6,135 first aid kits, each containing 1 100-tablet btl.; and 450 first aid kits, each containing 3 100-tablet btls., at Tulsa, Okla.

SHIPPED: Between 3-28-56 and 6-21-56, from Denver, Colo.

LABEL IN PART: (Btl.) "100 Water Purification Tablets For Purifying Drinking Water in Canteens Halazone P-sulfone-dichloramido-benzoic acid. Each Tablet Contains 0.004 GM (1/16 Grain) of Halazone with Sodium Carbonate, Sodium Chloride and Boric Acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 45 percent to 102.5 percent of the declared amount of halazone. The National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 8-17-56, N. Dist. Okla.

CHARGE: 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength, while held for sale, differed from the official standard.

DISPOSITION: 8-31-56. Default—destruction.

5209. Halazone tablets. (F. D. C. No. 39299. S. No. 56-011 M.)

QUANTITY: 5,770 100-tablet btls. at Streator, Ill.

SHIPPED: 5–8–56, from Pauline, Kans.

LABEL IN PART: (Btl.) "Water Purification Tablets For Purifying Drinking Water in Canteens * * * Halazone * * * (P-sulfonedichloramido-benzoic acid) Each Tablet Contains 0.004 gm. (1/16 grain) of Halazone," "Tablets Water Purification For Treating Water in Canteens * * * (p-sulfonedichloramido-benzoic acid 0.004 gm.)," or "Water Purification Tablets For Purifying Drinking Water in Canteens Halazone P-sulfonedichloramido-benzoic acid * * * Each Tablet Contains 0.004 Gm. (1/16 Grain) of Halazone."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 18.17 percent to 104 percent of the declared amount of halazone. The National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 7–12–56, N. Dist. Ill.

CHARGE: 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength, while held for sale, differed from the official standard.

DISPOSITION: 8–16–56. Default—destruction.

5210. Halazone tablets. (F. D. C. No. 39461. S. No. 52–193 M.)

QUANTITY: 1,108 first aid kits, each containing 1 bottle, of *halazone tablets* at New York, N. Y.

SHIPPED: 2–24–56, from Tulsa, Okla.

LABEL IN PART: (Btl.) "100 Water Purification Tablets * * * Halazone * * * Each table contains 0.004 Gm. (1/16 grain) of Halazone with Sodium Borate and Chloride."

RESULTS OF INVESTIGATION: Examination disclosed that, in addition to the *halazone tablets*, each of the kits contained 1 bottle of insect repellent; 1 small first aid dressing, Carlisle Model; 1 box with 6 iodine swabs; 5 adhesive absorbent bandages; and 1 tube of boric acid ointment.

Analysis showed that the tablets contained from 72 to 91 percent of the declared amount of halazone. The National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 9–20–56, S. Dist. N. Y.

CHARGE: 501 (b)—the strength and quality of the tablets, while held for sale, differed from the standard set forth in the National Formulary for *halazone tablets*.

DISPOSITION: 10–17–56. Consent—claimed by Dadourian Export Corp., New York, N. Y. The first aid kits were reconditioned by removal and destruction of the *halazone tablets* and the adhesive absorbent bandages and first aid dressings contained in the kits.

5211. Clinical thermometers. (F. D. C. No. 39514. S. No. 51–032 M.)

QUANTITY: 135 *clinical thermometers* at East Pasadena, Calif.

SHIPPED: 4–25–56 and 6–13–56, from New York, N. Y., by Philbern Thermometer Co., Inc.

LABEL IN PART: (Ctn.) "Philbern U-C Guaranteed fever thermometer."

ACCOMPANYING LABELING: Leaflet entitled "Certificate of Examination Clinical Thermometer."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 4 thermometers failed to comply with the requirement for accuracy, one of which failed also to comply with the test for retreating index, specified in CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1–52.

LIBELED: 10–11–56, S. Dist. Calif.

CHARGE: 501 (c)—the quality of the article fell below that which it purported and was represented to possess; and 502 (a)—the statement appearing in the accompanying leaflet, namely, "This thermometer has been tested and found to comply with the requirements of Commercial Standard CS1–52," was false and misleading since it was contrary to fact.

DISPOSITION: 11–13–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5212. Black tablets and red tablets for use in the treatment of cancer. (F. D. C. No. 37908. S. Nos. 4–052/3 M.)

QUANTITY: 10 ctns., 26,332 *black tablets* each, and 4 drums, 62,900 *red tablets* each, at Portage, Pa., in possession of Hoxsey Cancer Clinic.

SHIPPED: Between 3–4–55 and 3–11–55, from Detroit, Mich.

LABEL IN PART: (Ctn.) "Hoxsey—100 SC Tablets Black Control Number 06980"; (drum) "Name Special Tablets SC Red 06949 Lactotaba [sic]."

ACCOMPANYING LABELING: The leaflets, reprints, and magazine accompanying the tablets are enumerated below, in the court's instructions to the jury.

LIBELED: 3–25–55, W. Dist. Pa.; amended, 6–5–56.

CHARGE: The tablets were charged to be misbranded under 502 (a). The charges are stated in the court's instructions to the jury and in the court's decision of 5–28–57, both set forth below.

DISPOSITION: The Hoxsey Cancer Clinic, Portage, Pa., and Dr. Newton C. Allen filed as claimants. On 4–15–55, claimants filed exceptions, a motion for a more definite statement, and a motion to dismiss. Thereafter, on 4–26–55, claimants filed a motion for an order for the protection of the parties and deponents and to quash subpoena ad testificandum and subpoena duces tecum.

On 5–18–55, the court handed down the following memorandum opinion:

MILLER, *District Judge:* "This is a motion and a supplemental motion 'for an Order for the Protection of the Parties Deponents and to Quash Subpoena ad Testificandum and Subpoena Duces Tecum.' As the caption indicates, this action was instituted by a libel against 10 cartons of tablets. The libel was filed March 25, 1955. A pleading entitled 'Exceptions, motion for more definite statement and motion to dismiss' was filed April 15, 1955. The questions raised by the exceptions pleading have not been decided by the court and are not discussed herein, for the reason that counsel for the deponents and for the government have agreed that the exceptions should be argued at the regular argument day of this court, rather than at the time fixed for argument of the instant motions. (R. 26). On April 19, 1955, there was filed a notice to take depositions pursuant to Fed. R. Civ. P. 30 in Room No. 3, United States Court House, Pittsburgh, Pennsylvania, (Allegheny County), upon Dr. Newton C. Allen, Senator John J. Haluska, Dr. Gertrude N. Chalmers, Dr. J. H. Benko, and Ann Shatrosky, R. N., all of Portage, Cambria County, Pennsylvania. On April 21, 1955, the above-named individuals were served with subpoenas requiring them to appear as indicated by the afore-

*See also Nos. 5202, 5204, 5207, 5211.

mentioned notice for the taking of depositions and to bring with them specified records, memoranda and other documents.

"The instant motion of the deponents was filed on April 26, 1955, and argument was heard thereon on April 28, 1955. It was then agreed (R. 24, 25) that the argument should be continued, as requested by counsel for deponents, until May 10, 1955, with the understanding and agreement of counsel that if the ruling should be that the depositions are to be taken, the records and witnesses would be available on the following morning at 10:00 o'clock at any place that the court would designate and that no further subpoenas or notice would be necessary to any of the parties. At the argument on May 10, 1955, counsel for the deponents filed the instant supplemental motion asserting for the first time, in support of the relief requested, the deponents' constitutional privilege against self incrimination. No order was made because the court wished to reserve judgment on the new issue thus raised.

"The questions raised by deponents' first motion will be discussed first.

"1) Deponents assert that the notice to take depositions and the subpoenas are void because, at this stage of the cause, the admiralty rules, rather than the Rules of Civil Procedure, are applicable. This contention must fail. United States v. 5 cases, 179 F. 2d 519 (2d Cir.), *cert. denied* 339 U. S. 963 (1950); United States v. 38 Cases, 99 F. Supp. 460, 464–65 (S. D. N. Y. 1951).

"2) Deponents object to the taking of depositions other than in Cambria County, the county seat of which is approximately 70 miles from Pittsburgh. It is true that under Fed. R. Civ. P. 45 (d) (2), witnesses who are not parties should not be required to appear for the taking of depositions other than in the county where they reside or are employed or transact their business, without an order of court. However, the question now is whether such an order should be made.

"The words 'convenient place' referred to in Fed. R. Civ. P. 45 (d) (2) do not refer solely to the convenience of the witnesses. Producers Releasing Corp. de cuba v. PRC Pictures, Inc., 176 F. 2d 93 (2d Cir. 1949). Because of the issues raised by deponents' supplemental motion and the opinion of this court, indicated below, as to the proper procedure for the raising of such issues, it is apparent that the only convenient place in this district for the discovery which the government seeks is at the place where this court sits, at Pittsburgh, Pennsylvania. Apparently, at least one court has uniformly followed the practice of having depositions taken at the court house in the constructive presence of the court so that objections to questions can be ruled on at once. Kirshner v. Palmer, 7 F. R. D. 252–53 (S. D. N. Y. 1945). This procedure seems appropriate in the instant case.

"3) Deponents have urged that depositions should not be taken while their exceptions are pending. This assertion is foreclosed by the agreement of counsel referred to above. (R. 26). In any event, the court is of the opinion that discovery should not be postponed merely because exceptions to the libel are pending in the instant case.

"4) Deponents assert that the discovery sought is intended to harass and embarrass them. However, it has not been shown in what respects the discovery sought is so harassing or embarrassing as to preclude the taking of dispositions or the production of documents. Deponents' assertion is, therefore, rejected without prejudice to their right to raise the question of harassment or embarrassment with specificity at the time of taking of depositions.

"5) The same may be said with respect to the claim that the notice and subpoenas are unreasonable, oppressive, too sweeping in their terms, and call for irrelevant matter.

"6) It is claimed that the records sought for production are not in the 'possession and control' of any of the deponents other than Dr. Allen. If the records are not in the possession *or* control of such other deponents, that is clearly a matter to be asserted in answer to the discovery sought; it in no way renders the subpoenas or the notice to take depositions objectionable.

"7 & 8) The objections that the discovery sought is violative of doctor-patient and/or attorney-client privileges may be asserted at the time and place of the taking of depositions, at which time deponents may show in what respects the disclosure of what information or records would be violative of what privileges.

"9) The supplemental motion asserts that if the deponents are required to answer, they will be compelled to testify against themselves in violation of

their constitutional privilege against self incrimination. It has often been held that the privilege against self incrimination is a personal one which may be raised only for oneself and by oneself and not by one's counsel. See Haines v. United States, 188 F. 2d 546, 551 (9th Cir.), *cert. denied* 342 U. S. 888 (1951); Ziegler v. United States, 174 F. 2d 439, 447 (9th Cir.), *cert. denied* 338 U. S. 822 (1949); United States v. Johnson, 76 F. Supp. 538, 540 (M. D. Pa. 1947); Board of Comm'rs v. Maretti, 117 Atl. 482, 487 (N. J. Ch. 1922). As stated in Communist Party v. McGrath, 96 F. S. 47, 52 (D. C.), *pet. for extension of stay order denied* 340 U. S. 950 (1951):

> A witness' privilege against self-incrimination must be claimed personally, at the time the alleged incriminating questions are propounded, not before they are asked at all.

This court is of the opinion that the privilege against self incrimination cannot properly be raised by the instant motion for a protective order under Fed. R. Civ. P. 30 and to quash the subpoena, but rather, that the witnesses must refuse to answer and produce records, claiming the privilege under oath, whereupon the government may test the claimed privilege by a motion for an appropriate order, United States v. Fishman, 15 F. R. D. 151 (S. D. N. Y. 1953); Mumford v. Croft, 93 A. 2d 506 (Del. Super. Ct. 1952). As stated in the Mumford case at 93 A. 2d 507–08:

> Although objections to interrogatories have been permitted as a means of claiming the privilege against self-incrimination, I am of the opinion that the assertion of the privilege, as a reason for not answering interrogatories in a civil case, is not properly before the Court upon objections filed by the attorney for the party claiming the privilege. The privilege is a personal one to be claimed by the party and not by his attorney. . . . The privilege is an "option of refusal, not a prohibition of inquiry." The plaintiffs are entitled to have the oath of the defendants either in answering the interrogatories or in asserting their privilege not to answer. If either of the defendants were called by the plaintiffs at the trial of this case, he or she would be obliged to take the oath, await the question and then claim the privilege under oath. . . . The rules of evidence which would govern privileged matters at trial govern such matters when they arise during discovery. . . . I think, therefore, that the issue of whether the defendants should be obliged to answer these interrogatories should be presented by a refusal to answer and a claim of privilege under oath, followed by an application by the plaintiffs, under Rule 37 (a), for an order compelling an answer. . . .

"Paul Harrigan & Sons, Inc. v. Enterprise Animal Oil Co., 14 F. R. D. 333 (E. D. Pa. 1953) and Porter v. Heend, 6 F. R. D. 588, 590 (N. D. Ill. 1947) appear to be authority for the proposition that the privilege against self incrimination could be properly raised by the instant motions. However, neither the Porter nor the Harrigan & Sons case discusses an assertion that the claim of privilege must be made personally and under oath, and no case suggests that to follow the procedure outlined in the Fishman and Mumford cases would be a violation of constitutional rights, an abuse of discretion, or an unwise procedure. Indeed, it is generally held that it is not a violation of constitutional rights to require witnesses to appear and be sworn. United States v. Benjamin, 120 F. 2d 521, 522 (2d Cir. 1941); Mulloney v. United States, 79 F. 2d 566, 578–80 (1st Cir. 1935); O'Connell v. United States, 40 F. 2d 201, 205 (2d Cir.), *appeal dismissed per stipulation* 296 U. S. 667 (1930); United States v. Haas, 126 F. Supp. 817, 818 (S. D. N. Y. 1954); United States v. Scully, 119 F. Supp. 225, 227 (S. D. N. Y. 1954); United States v. Manno, 118 F. Supp. 511, 517 (N. D. Ill. 1954); United States v. Mangiaracina, 92 F. Supp. 96, 97 (W. D. Mo. 1950); United States v. Miller, 80 F. Supp. 979, 981 (E. D. Pa. 1948); United States v. Wilson, 42 F. Supp. 721, 722 (D. Del. 1942); United States v. Burk, 41 F. Supp. 916, 918 (D. Del. 1941).

"This court is of the opinion that the procedure outlined in the Fishman and Mumford cases is sound and appropriate in the case at bar. Accordingly, an order is entered requiring deponents to appear for the taking of depositions at the United States Courts and Post Office Building in Pittsburgh, Pennsylvania, and to bring with them those records specified in the subpoenas which

are in their possession or control. Upon being sworn, deponents may raise the questions which they have sought to raise by the instant motions, not inconsistently with this opinion. The question of whether the records sought should be produced to the interrogating party, or to the court, may be determined when and if questions of privilege are raised. See Brown v. United States, 276 U. S. 134, 144 (1928); Consolidated Rendering Co. v. Vermont, 207 U. S. 541, 552–53 (1908); United States v. White, 137 F. 2d 24, 26 (3d Cir. 1943), *rev'd on other grounds* 322 U. S. 694 (1944); Corretjer v. Draughon, 88 F. 2d 116 (1st Cir. 1937); 8 *Wigmore, Evidence* § 2200 (5) (3d ed. 1940).

"An appropriate order is entered."

After hearing arguments on the exceptions to the libel, the court entered the following memorandum opinion on 8–2–55:

MILLER, *District Judge:* "This case is before the court upon 'exceptions, motion for more definite statement, and motion to dismiss,' filed by Hoxsey Cancer Clinic, Portage, Pennsylvania, and Dr. Newton C. Allen, the claimants herein. The court's jurisdiction is based upon the Federal Food, Drug, and Cosmetic Act, § 304 (a), 52 Stat. 1044 (1938), as amended, 21 U. S. C. A. § 334 (a).

"The following facts appear from the libel: The articles in question were shipped from Detroit, Michigan, to Portage, Pennsylvania, at specified times via specified carriers, accompanied by specifically designated printed matter. The articles are drugs which were misbranded while held for sale after shipment in interstate commerce, within the meaning of the Federal Food, Drug, and Cosmetic Act, in that the articles are the essential part of the Hoxsey Treatment for Internal Cancer, and the specified printed matter accompanying the drugs contains representations and suggestions that the Hoxsey Treatment is adequate and effective in the treatment of internal cancer in humans, which representations and suggestions are false. The articles are further misbranded in that a specified leaflet accompanying them contains statements which represent and suggest that, as the result of litigation with the United States Government, there is in effect a decree which permits the offering of the Hoxsey Treatment for Internal Cancer as beneficial, effective, and having value in the treatment of cancer so long as qualifying statements are made to the effect that there is a conflict of medical opinion as to the truth of such representations. Such statements are false and misleading since, as the result of such litigation, there is not in effect such a decree but, on the contrary, the United States Court of Appeals for the Fifth Circuit has rendered an opinion which forbids the use of any claims, however qualified, that the Hoxsey Treatment for Internal Cancer would be effective in the treatment of cancer. The injunctive decree under which the Hoxsey Cancer Clinic is now operating, entered October 26, 1953, contains an unequivocal prohibition against any labeling claims for the Hoxsey Treatment for Internal Cancer, or any like drugs or combination of drugs, in the treatment of cancer. The articles are in the possession of Hoxsey Cancer Clinic, Portage, Pennsylvania, or elsewhere within this court's jurisdiction. The articles are held illegally within this court's jurisdiction and are liable to seizure and condemnation pursuant to the Federal Food, Drug, and Cosmetic Act.

"At the oral argument upon the exceptions, a number of the paragraphs thereof were waived by counsel for claimants. The remaining paragraphs which were not waived are as follows:

> 3. The facts averred in the libel are insufficient to constitute a cause of action.
> 7. The third paragraph of the libel does not sufficiently, fully and distinctly allege the manner in which the alleged leaflets are cause of "misbranding" of the seized drugs and "labeling thereof" under the Federal Food, Drug and Cosmetic Law.
> 9. Paragraph number three of the libel does not allege any facts to establish sufficiently, fully and distinctly how and in what manner the seized drugs are the "essential part of the Hoxsey Treatment for Internal Cancer" administered by the Hoxsey Cancer Clinic of Portage, Pennsylvania.

11. Paragraph number three of the libel does not allege any facts to establish sufficiently, fully and distinctly how and why the Hoxsey treatment for Internal Cancer as administered by the Hoxsey Cancer Clinic, Portage, Pennsylvania, is not adequate and effective in the treatment of internal cancer in humans.
12. Paragraph number four does not sufficiently, fully and distinctly state how and why the said seized articles are the essential part of the Hoxsey Treatment for Internal Cancer, nor does said paragraph number four state sufficiently, fully and distinctly the specific statements of the various leaflets which libellant avers substantiate the allegations of misrepresentation and falsity, so set forth.
13. The allegations of paragraph number four do not sufficiently, fully and distinctly reveal how the said Decree of the United States Court of Appeals for the Fifth District apply and affect the Hoxsey Cancer Clinic of Portage, Cambria County, Pennsylvania.
14. The libel does not have attached to it the various leaflets, written, printed and graphic matter, which are alleged to have accompanied the seized drugs and which are alleged to constitute mislabeling and misbranding under the Federal Food, Drug and Cosmetic Act.
15. The said libel does not contain a list or description identifying the ingredients of the seized drugs.
18. Paragraph number three of the libel does not sufficiently, fully and distinctly reveal, how, in what manner and how the seized drugs are held for sale after shipment in interstate commerce within the meaning of the Federal Food, Drug and Cosmetic Act.

"§ 304 (a) of the act, *supra*, 21 U. S. C. A. § 334 (a), provides:

> Any article of . . . drug . . . that is . . . misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. . . .

"§ 502 of the act, 52 Stat. 1050, as amended, 21 U. S. C. A. § 352 provides:

> A drug . . . shall be deemed to be misbranded—
> (a) If its labeling is false or misleading in any particular.

"§ 201 of the act, 52 Stat. 1041, as amended, 21 U. S. C. A. § 321 (m), provides:

> The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"The elements thus specified as prerequisite to a 'cause of action' clearly are all alleged in the libel. The contention that the facts averred in the libel are insufficient to constitute a cause of action is without merit.
"The remaining paragraphs of the exceptions relate to claimants' contention that the libel is insufficiently definite and specific under Admiralty Rule 21. Claimants contend, and plaintiff has not disputed, that the question of the sufficiency of the allegations has been properly raised under Admiralty Rule 27 or under Fed. R. Civ. P. 12 (e).
"What has been said in *Marshall Hall Grain Co.* v. *United States Shipping Board Emergency Fleet Corp.*, 14 F. 2d 141, 142 (D. Mass. 1926) is appropriate here:

> It must be quite apparent from the above summary of the allegations that, if the libelants' proofs come up to their allegations, it would be impossible to rule, as a matter of law, that each had not made out a prima facie case of liability, entitling it to relief in the admiralty court.

"The objection that the libel alleges conclusions of law is without merit. Allegations in the words of the applicable statute are proper. *United States* v. *The Antoinetta*, 153 F. 2d 138, 141–42 (3d Cir. 1945), *cert. denied* 328 U. S.

863, *rehearing denied* 329 U. S. 820 (1946). In *Seven Cases* v. *United States*, 239 U. S. 510, 518 (1916), the Court held, with respect to allegations which appear to have been no more detailed than those here involved:

> With respect to the sufficiency of the averments of the libels, it is enough to say that these averments should receive a sensible construction. There must be a definite charge of the statutory offense, but we are not at liberty to indulge in hypercriticism in order to escape the plain import of the words used.

"Clearly, all of the matters required to be averred under Admiralty Rule 21 have been averred; the question raised by claimants relates to the specificity with which such matters must be pleaded. In *Colonial Sand & Stone Co.* v. *Muscelli*, 151 F. 2d 884, 885 (2d Cir. 1945), the court held:

> True, it has been a common custom in the admiralty not to confine pleadings to the "ultimate," "constitutive," or "operational," facts on which the right or defense depends, as is required in other branches of the law; but to set out a discursive narrative of the pleader's version of the events. That custom is more honored in the breach than in the observance; but, assuming that long tolerance has sanctioned it, there is no warrant for making it compulsory, and every reason to sustain a pleading which is adequate under ordinary canons.

"No reason has been suggested to the court why any greater specificity should be required in a libel than in a complaint. The discovery rules of the Federal Rules of Civil Procedure are as available to claimants in this action as they are to parties in an action instituted by complaint, and much of the information which claimants seek to have libelant plead can be obtained through the use of the discovery rules. *Cf. Prescan* v. *Aliquippa & Southern R. R.*, 16 F. R. D. 272 (W. D. Pa. 1954); *Byers* v. *Olander*, 7 R. F. D. 745, 746 (W. D. Pa. 1948). The pleading here attacked is more than sufficient 'to afford fair notice to the adversary of the nature and basis of the claim asserted and a general indication of the type of litigation involved.' *Cf. Continental Collieries, Inc.* v. *Shober*, 130 F. 2d 631, 635 (3d Cir. 1942).

"For the foregoing reasons claimants' exceptions must be dismissed. An appropriate order is entered."

Thereafter, on 9–14–55, the claimant filed a motion to correct the transcript relating to depositions and, on 9–22–55, filed a motion to suppress the deposition of Harry M. Hoxsey which had been taken on 9–15–55, in Dallas, Tex. The Government filed a motion to compel deponents to answer oral interrogatories and a motion to compel deponents to obey subpoenas duces tecum. On 2–29–56, the court handed down the following memorandum opinion:

Miller, *District Judge:* "This case is now before the court upon motions of Newton C. Allen, D. O., a claimant herein, to suppress the deposition of Harry M. Hoxsey, N. D., taken September 15, 1955, in Dallas, Texas, to compel transcription and delivery of deposition, and to correct the transcript relating to depositions, and upon libelant's motion to compel deponents to answer oral interrogatories and to compel two of the deponents to obey subpoenas duces tecum.

"With respect to the motion to suppress the Hoxsey deposition, government counsel have admitted the truth of the averment that they failed to give notice of the taking of the deposition as required by Fed. R. Civ. P. 30 (a). Therefore, Dr. Allen's motion to suppress the Hoxsey deposition will be granted. *Associated Transport, Inc.* v. *Riss & Co.*, 8 F. R. D. 99 (N. D. Ohio 1948).

"Claimant's motions to compel transcription and delivery of deposition and to correct the transcript relating to depositions have not been mentioned by counsel in argument or briefs. Therefore, those motions will be dismissed without prejudice.

"The deponents, Allen, Haluska, Shatrosky, Benko, and Chalmers, were by subpoenas served upon them and by an order of this court of May 18, 1955,

required to appear for the taking of depositions by government counsel and to bring with them records as specified by the subpoenas. Deponents appeared for the depositions and were duly sworn, but refused to produce the records and refused to answer many questions. Extensive objections to producing the records and answering the questions were made by and on behalf of deponents, the only objection of any substance being the claim of privilege against self incrimination.

"With respect to deponent Shatrosky, however, there were no unanswered questions to which the government has moved to compel answers. Libelant's claim is that deponent Shatrosky answered 'I don't know' to a number of questions the answers to which she must have known. It is not absolutely clear from the transcript of her testimony that this is so. Moreover, this is not a motion to punish for contempt such as was made in the case upon which libelant relies: *Crosley Radio Corp.* v. *Hieb*, 40 F. Supp. 261 (S. D. Iowa 1941). There being no questions unanswered by deponent Shatrosky to which libelant has moved the court to compel answers, the motion to compel answers will be denied as to her.

"With respect to deponents Benko and Chalmers, the court is of the opinion that the claim of privilege must be fully sustained, and the government's motion to compel answers must be denied. As stated in *Hoffman* v. *United States*, 341 U. S. 479, 486–87 (1951):

> If the witness, upon interposing his claim, were required to prove the hazard in the sense in which a claim is usually required to be established in court, he would be compelled to surrender the very protection which the privilege is designed to guarantee. To sustain the privilege, it need only be evident from the implication of the question, in the setting in which it is asked, that a responsive answer to the question or an explanation of why it cannot be answered might be dangerous because injurious disclosure could result.

"In the setting of this case, the court is of the opinion that deponents might reasonably fear that answering any questions might be dangerous. Deponents are all allegedly or admittedly officers or employees of the Hoxsey Cancer Clinic of Portage, which is alleged in this action to have acquired certain drugs in interstate commerce and to have falsely represented the same as being useful in the treatment of cancer. Thus, the gist of this action is a federal crime. Act of June 25, 1938, § 303, 52 Stat. 1043, as amended, 21 U. S. C. A. § 333. Therefore, the more germane libelant's questions may be to the subject matter of this action, the more readily apparent it is that answers thereto could be incriminating. Deponents thus find themselves in the situation discussed in *Maffie* v. *United States*, 209 F. 2d 225, 228–29 (1st Cir. 1954):

> The witness may have reason to believe that he himself is under suspicion and that it will be the purpose of the interrogator to worm out of him all the self-incriminatory disclosures possible. In that case, the situation of the witness approaches that of an accused person at a criminal trial, who may elect to keep silent altogether. The witness may be willing to answer certain formal preliminary inquiries, as to matters generally known, such as his name, residence, age, *et cetera*. But he may have a justified apprehension of danger in answering further. He may not have the acuteness to see what an innocuous-looking question, put by a resourceful cross-examiner, is leading up to. Yet he might not be unreasonable in believing that the question was asked for a purpose and that the purpose was to lead him into a booby trap in which he would make some disclosures useful to the prosecution in weaving a case against him. Just where the line should be drawn in such a case, in the application of the privilege, might be a question; but it is certainly clear that it should be drawn well short of the point where the interrogator might have a substantial chance of striking pay dirt.

"*See also*, *Aiuppa* v. *United States*, 201 F. 2d 287, 294 (6th Cir. 1952); *Marcello* v. *United States*, 196 F. 2d 437, 441 (5th Cir. 1952).

"The same considerations apply to the motion to compel answers with respect to deponent Allen, except with reference to certain unprivileged mat-

ters which will be discussed below. The court has not failed to note the extraordinary position taken by Dr. Allen in this action. Dr. Allen, as claimant of the articles seized in this action, has filed an answer to the libel and a number of motions. Yet, upon the taking of Dr. Allen's deposition, he not only failed to claim the seized articles, but refused to answer questions which would connect him in any way with them. However, whatever may be the effect of Dr. Allen's ambivalent position on his standing as a party to this action, the court is of the opinion that it cannot be held to abrogate his constitutional privilege.

"Libelant earnestly contends that deponent Haluska's claim of privilege was not made in good faith and should not be sustained because of certain public statements made by him shortly after the taking of his deposition on May 20, 1955. It appears from the Legislative Journal for May 24, 1955, for the Senate of the Commonwealth of Pennsylvania, that Senator Haluska represented on the floor of the Senate that he had been 'compelled' to 'use the Fifth Amendment' in this case in order to protect the 'private communications' of the Hoxsey Cancer Clinic's patients, and that he would 'talk freely' if only this court would order the records in question to be brought in. Of course, as libelant contends, such representations were patently absurd: (1) Senator Haluska had already been ordered by this court on May 18, 1955, to appear for the taking of his depositions and to bring with him the records listed in the subpoena; (2) a great many of those records and most of the questions which he refused to answer had nothing to do with the clinic's patients; (3) the blanket patient-physician privilege which he asserted does not exist under the laws of Pennsylvania (Act of June 7, 1907, P. L. 462, § 1, 28 Pa. P. S. § 328) or of the United States; (4) a desire to protect the private communications of others, clearly constitutes no proper basis for the claim of privilege against self incrimination.

"Two days later, May 26, 1955, in Senator Haluska's newspaper column, 'AS I SEE IT,' in the Portage Dispatch, the following statement appears:

> As the administrator of this clinic, I assure the people that I have nothing to hide, and I shall only be too happy to tell the government, in fact, the entire world of all our proceedings at our institution. I shall be happy to tell the government just who the Hoxsey Clinic of Portage is. There are no secrets in our lives but we want to make these announcements, not to a few attorneys, but to a jury of men and women who would be privileged to decide honestly whether or not the Hoxsey Clinic has given false hope to those poor victims who are told they must die, or whether they have been treated successfully by having their lives extended and pain relieved.

"Of course, the proper time and place for the Senator to have told 'the government, in fact, the entire world of all our proceedings at our institution' was upon his deposition under oath, taken pursuant to order of this court, at which time the Senator was willing to tell substantially nothing about his connection with the clinic or its affairs. If the Senator's newspaper statement could be believed, it would appear that his claim of privilege against self-incrimination was based entirely upon a contemptuous disregard for and refusal to comply with the lawful discovery procedures and order of this court.

"This court cannot condone or justify the flagrant and cynical abuse of the great constitutional privilege evidenced by Senator Haluska in this case. But an insuperable difficulty inheres in the government's position. To require Senator Haluska to show which of the conflicting statements which he has made in support of his refusal to answer questions and produce documents is the true one would be tantamount to requiring him to show not merely that the discovery to which he has refused to submit *could* be incriminating, but that it *would* be incriminating. So to require would be to compel him to incriminate himself in order to sustain his privilege not to do so. Therefore, the court is of the opinion that the government's motion as to deponent Haluska must be denied, except with respect to unprivileged matters.

"The unprivileged matters to which the court has alluded in connection with deponents Allen and Haluska are the records of the Hoxsey Cancer Clinic of Portage and/or of Hoxsey Cancer Clinic, Inc. It has been abundantly

shown that the scope of the activities and membership of the clinic in Portage are of such an impersonal character that the clinic cannot be said to embody the purely personal and private interests of its constituents. Therefore, no claim of privilege with respect to the records of the clinic can be sustained, regardless of whether such records may incriminate deponents as individuals or as officers or employees of the clinic. *See Rogers* v. *United States*, 340 U. S. 367, 371–72 (1951); *United States* v. *Fleischman*, 339 U. S. 349, 358 (1950); *United States* v. *White*, 322 U. S. 694, 701, 704 (1944); *United States* v. *Field*, 193 F. 2d 92 (2d Cir.), *cert. denied* 342 U. S. 894 (1951), *cert. dismissed* 342 U. S. 908 (1952); *Fulford* v. *United States*, 155 F. 2d 944, 947 (6th Cir. 1946); *United States* v. *Onassis*, 133 F. Supp. 327 (S. D. N. Y. 1955); *United States* v. *Onassis*, 125 F. Supp. 190, 210 (D. C. D. C. 1954); *but cf. United States* v. *Lawn*, 115 F. Supp. 674 (S. D. N. Y. 1953); *In re Subpoena Duces Tecum*, 81 F. Supp. 418 (N. D. Cal. 1948).

"The lists of records required by the subpoenas are not explicitly limited to records of the Hoxsey Cancer Clinic of Portage and/or of the Hoxsey Cancer Clinic, Inc. The order enforcing the subpoenas duces tecum as to deponents Allen and Haluska must be so limited. However, it is for the court, not the deponents, to determine questions of ownership and privilege. Therefore, deponents shall be ordered to submit the records under subpoenas as to which they may claim ownership solely in their individual capacities to the court for its determination of the validity of any such claim. *See Brown* v. *United States*, 276 U. S. 134, 144 (1928); *Consolidated Rendering Co.* v. *Vermont*, 207 U. S. 541, 552–53 (1908); *United States* v. *White*, 137 F. 2d 24, 26 (3d Cir. 1943), *rev'd on other grounds* 322 U. S. 694, *supra; Corretjer* v. *Draughon*, 88 F. 2d 116 (1st Cir. 1937); 8 *Wigmore, Evidence* § 2200 (5) (3d ed. 1940).

"With respect to any of the clinic's records under subpoena which are not produced, deponents Allen and Haluska may be compelled to answer under oath questions relating to the location and custody of such records; with respect to records which are produced, they may be required under oath to answer questions relating to their identity and authenticity. *See United States* v. *Field*, *supra*; *Pulford* v. *United States*, *supra*. 155 F. 2d at 947; *Lumber Products Ass'n* v. *United States*, 144 F. 2d 546, 553 (9th Cir. 1944), *rev'd on other grounds sub nom. United Brotherhood of Carpenters* v. *United States*, 330 U. S. 395 (1947); *Carolene Products Co.* v. *United States*, 140 F. 2d 61, 66 (4th Cir.), *aff'd on other grounds* 323 U. S. 18 (1944); *United States* v. *Illinois Alcohol Co.*, 45 F. 2d 145 (2d Cir. 1930), *cert. denied* 282 U. S. 901 (1931); *United States* v. *Austin-Bagley Corp.*, 31 F. 2d 229 (2d Cir. 1929); *United States* v. *Sclafani*, 126 F. Supp. 654 (E. D. N. Y. 1954); *United States* v. *Lawn*, *supra*, 115 F. Supp. at 677; *United States* v. *Greater New York Live Poultry Chamber of Commerce*, 34 F. 2d 967 (S. D. N. Y. 1929), *aff'd on other grounds* 47 F. 2d 156 (2d Cir.), *cert. denied* 283 U. S. 837 (1931); *Cf. Heike* v. *United States*, 227 U. S. 131 (1913); *Wilson* v. *United States*, 221 U. S. 361 (1911).

"Libelant also contends that deponents Allen and Haluska have waived their privilege against self incrimination with respect to certain topics through statements and answers which were made by them. However, the answers which libelant seeks to compel might well be more incriminating than the answers already given. To hold that deponents have waived their privilege in these circumstances would serve only to cause witnesses in other cases justifiably to fear to answer non-incriminating questions lest they be held to have waived their privilege not to answer incriminating questions. This is not a case where witnesses have given self incriminating answers and have then refused to disclose details which would not further incriminate them. *See, e. g., Rogers* v. *United States*, *supra*, 340 U. S. at 372–75.

"Libelant may submit an order in conformity with this opinion. An order with respect to claimant's motions is entered."

On 4–2–56, the court ordered Newton C. Allen and John J. Haluska to respond to the subpoenas duces tecum that had been served on 4–18–55.

The case came on for trial on 10–8–56. After submission of evidence by both parties, the court instructed the jury on 11–15–56, as follows:

MILLER, *District Judge:* "Members of the jury, under the Constitution of the United States, Congress has been given power to regulate commerce between

the various states. In the exercise of its constitutional powers, Congress has enacted the Federal Food, Drug and Cosmetic Act, sometimes referred to as the Food and Drug Act, one of the purposes of which is to keep interstate commerce free from misbranded articles of the type specified by the statute, for the protection of the general public.

"In this case, we are involved with a requirement of the law that a consumer in any applicable instance must be both adequately and truthfully informed of what he is purchasing.

"One of the means by which the provisions of the law may be enforced is through a seizure and condemnation procedure, in which the Government takes possession of the articles claimed to be misbranded and if, after a trial such as this, it is found that the requirements of the statute are violated, such articles may be destroyed under an order of condemnation.

"The seizure and condemnation procedure is the one which the Government is following here. The statute in part provides as follows:

> Any article of food, drug, device or cosmetic that is . . . misbranded when introduced into or while in interstate commerce or while held for sale . . . after shipment in interstate commerce shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found.

"The present lawsuit is confined to the alleged misbranding of a large quantity of black and red pills, contained in a number of cartons and drums found upon the premises of the Hoxsey Cancer Clinic at Portage, Pennsylvania, and there seized by the Government pursuant to a warrant of seizure and monition issued out of this court.

"The warrant of seizure and monition was authorized by this court upon a libel of information filed by the Government, in which the Government claims, 1. That the pills which were seized and which are now in this courtroom are drugs within the meaning of the Federal Statute; 2. That at the time of the seizure of the pills at the Hoxsey Cancer Clinic at Portage, Pennsylvania, they were being held for sale, after having been shipped in interstate commerce; 3. That at the time of their seizure at the Hoxsey Cancer Clinic in Portage, Pennsylvania, the pills were accompanied by certain pieces of written, printed and graphic matter, which were used by the Hoxsey Cancer Clinic to promote the sale of the Hoxsey internal cancer treatment, and that the printed materials constituted labeling within the statute.

"It is contended that the alleged labeling contained statements and representations causing the pills to be misbranded while held for sale, after shipment in interstate commerce.

"An answer to the libel was filed by the Hoxsey Cancer Clinic of Portage, Pennsylvania, and Dr. Newton C. Allen, Medical Director of the Clinic, as owner and claimant of the pills in question.

"The answer of the Clinic and Dr. Allen admits some of the allegations of the Government's libel but denies certain of the material averments.

"The parties have agreed that the pills in question are drugs within the meaning of the Federal Food and Drug Act. I instruct you that a drug, under the statute, is an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man.

"In connection with this stipulation of the parties, I call to your attention that there is no dispute about the ingredients of the pills. It is conceded that the red pills are composed of the following ingredients: Potassium iodide, red clover tops, stillingia root, berberis root, poke root, buckthorn bark, and pepsin; and the black pills are composed of these ingredients: Potassium iodide, licorice, red clover tops, burdock root, stillingia root, berberis root, poke root, cascara sagrada, prickly ash bark, and buckthorn bark.

"You may also take it as established as a fact in this case, in accordance with the admission of counsel for the claimant, that the red and black pills are the essential part of the Hoxsey cancer treatment for internal cancer in man.

"In order for the Government to succeed in this action, it is necessary that the pills were held for sale at the Hoxsey Cancer Clinic in Portage, Pennsylvania, after shipment in interstate commerce.

"In this case, it is admitted in the answer of Dr. Allen and the Hoxsey Cancer Clinic that the pills were shipped in interstate commerce, from the Testagar Company in Detroit, Michigan, to Portage, Pennsylvania, and therefore you need not concern yourself with the question of interstate transportation.

"The Hoxsey Cancer Clinic and Dr. Allen deny, however, that the pills were held for sale at the Portage Clinic, even though they had been shipped in interstate commerce. It is the position of the claimant and the Clinic that the articles of drugs, the red and black tablets, were not held for sale after shipment in interstate commerce, but were intended to be prescribed in conjunction with the treatment and methods suggested, after diagnosis of each case by a physician in charge.

"The concept, held for sale, as used in the Federal Statute, is a wide one and is not restricted simply to over-the-counter transactions. The act does not provide for any exception to be made in the case of drugs alleged to be misbranded, which are dispensed through a Clinic or a licensed physician.

"For the purpose of the Federal Food and Drug Act, every specified article which has been shipped in interstate commerce, which is not intended for consumption by the party who receives it, but is intended for a further distribution to others, is held for sale.

"It is immaterial, under the statute and under the evidence in the present case, if none of the pills involved was in fact sold or that some of them may have been given to patients free of charge. Under the law, it does not matter that the exact charge for pills cannot be identified. The fee charged at the Clinic included payment for the pills as well as for professional services. I therefore instruct you, under the law and under the evidence in this case, that these pills were held for sale at the Hoxsey Cancer Clinic, after having been shipped in interstate commerce.

"The essential issue in the case and the one which you must primarily concern yourselves with is whether the black and red Hoxsey pills are misbranded, under the Federal Statute.

"The statute provides that a drug is misbranded if its labeling is false or misleading in any particular.

"The term, labeling, as used in the Act, is not confined to the actual labels affixed to the containers of the drugs, but includes in addition to the actual labels such other written, printed or graphic matter, which accompanies the drug article which is held for sale after shipment in interstate commerce.

"In the present case, the Government says that an assortment of five different pamphlets, leaflets and magazines constitute the labeling which accompanied the drug in this case. Those pamphlets include the following:

"1. A leaflet, 'Hoxsey Cancer Clinic, 4507 Gaston Avenue, Dallas 10, Texas, Courtesy of Hoxsey Cancer Clinic, Portage, Cambria County, Pennsylvania, Specializing in the Treatment of Cancer, Precancerous and Chronic Diseases.' That has been marked Exhibit 24.

"2. A leaflet, 'Procedure and Information, Hoxsey Cancer Clinic, 911 Caldwell Avenue, Portage, Pennsylvania.' That is Exhibit No. 41.

"3. A leaflet, reprint from Man's Magazine, Volume 2, No. 6, August 1954, 'I Conquered Cancer,' by Allen Bernard, Exhibits 25 and 40.

"4. A leaflet, Hoxsey Cancer Clinic, 4507 Gaston Avenue, Dallas 10, Texas, 'Findings of the Doctors who Investigated the Facilities, Procedure and Treatment at the Hoxsey Cancer Clinic, April 10 and 11, 1954.' That is Exhibit 43.

"5. A magazine, The Defender Magazine, March 1955, Volume 29, No. 11, containing the speech by Senator Haluska. That is Exhibit 39.

"The exhibits which I have mentioned are here in this brown envelope for your convenience.

"The foregoing leaflets and magazines, all of which have been admitted in evidence, are of the type which under the law could constitute labeling. However, before such articles of literature would become labeling under the statute, you would have to find, by the preponderance of the credible evidence, that they accompanied the pills which were held for sale at the Hoxsey Cancer Clinic.

"That is the preliminary question you must decide with respect to the printed matter involved here.

"In determining whether or not this printed matter, or any of it, accompanied the drugs, you should keep in mind that it is not necessary that the alleged labeling be displayed with or physically attached to the drug. It is

sufficient if you find that the printed matter had a functional role in the distribution or sale of the Hoxsey red and black pills.

"In making this determination, you will consider all of the testimony bearing on the location of the leaflets and magazines, the contents of the same, the purposes for which they were intended, and the uses to which they were put.

"An article of literature accompanies an article of drug whenever its purpose is to supplement or explain the drug or its use. Thus, you must consider both the physical relationship between the literature and the drugs and the textual relationship of the literature with the drug.

"If, having done so, you are satisfied by the fair weight or preponderance of the credible evidence that the literature was associated with the drug in such a way as to become a part of the system by which the pills were distributed or sold to patients, you should conclude that such literature constitutes labeling.

"The evidence of the Government showed that copies of each of the pieces of literature involved here were found at the time of the seizure on the desk in the lobby of the Portage Clinic, near a waiting room which was used by the patients and other persons. Other copies of the Defender Magazine were found in a drug room at the back of the premises. The Government's evidence as to the location of the literature was not disputed, as I recall the evidence. From the fact of their presence on the table, it was intended that the articles would be read by patients and persons in the Clinic.

"The Government's contentions are that the aforesaid leaflets and magazines are false and misleading in three respects, which are set forth in detail in the libel. It is contended, one, that the foregoing leaflets and magazines contain representations and suggestions that the Hoxsey treatment for internal cancer is adequate and effective in the treatment of internal cancer in humans, which representations and suggestions are false and misleading, since it is contended that the Hoxsey treatment is not adequate and effective in the treatment of internal cancer in humans.

"The leaflet, 'Hoxsey Cancer Clinic, Dallas, Texas'—this is two—'Courtesy Hoxsey Cancer Clinic, Portage, Pennsylvania, Specializing in the Treatment of Cancer, Precancerous and Chronic Diseases,' represents and suggests that as the result of previous litigation there is in effect a decree which permits the offering of the Hoxsey treatment for internal cancer as beneficial and effective and having value in the treatment of cancer so long as qualifying statements are made to the effect that there is a conflict of medical opinion as to the truth of such representations.

"It is the Government's position that such representations are false and misleading because, as a result of such litigation, there is not in effect such a decree but a decree which forbids the making of any claim, however qualified, that the Hoxsey treatment for internal cancer is effective in the treatment of cancer and that the decree which pertains to the Hoxsey Cancer Clinic of Dallas, Texas, contains, actually, an unequivocal prohibition against any claims of effectiveness for the Hoxsey cancer treatment for internal cancer.

"3. The Government also contends that the leaflet, 'Hoxsey Cancer Clinic, Dallas, Texas, Courtesy of Hoxsey Cancer Clinic, Portage, Pennsylvania,' is false and misleading in that it represents and suggests that one Dr. Stanley Reimann made a survey of cancer cases in Pennsylvania and concluded that persons who received no treatment live longer than patients treated with surgery, X-ray and radium and that surgery, X-ray and radium generally do more harm than good in the treatment of cancer.

"The Government contends that these alleged representations are false and misleading in that Dr. Reimann made no such survey, with no such results, and that the article misrepresented Dr. Reimann's belief as to the effectiveness of X-ray, radium and surgery in the treatment of cancer.

"As I have stated, it is the Government's burden to establish its case by the fair weight or preponderance of the credible evidence. However, it is not required that the Government prove every one of the charges it has made in the libel. It is sufficient if the Government satisfies you, by the fair weight or preponderance of the credible evidence, that the alleged labeling was false and misleading in any one of the ways set forth, inasmuch as the Food and Drug Act applies to labeling that is false or misleading in any particular.

"It is therefore your duty to examine all of the evidence in the case and reach a conclusion whether or not the pills have been misbranded by the

alleged labeling. In performing your duty, there are certain rules and principles which you should keep in mind.

"You are the sole judges of the facts. In the exercise of this judgment, you must confine yourselves exclusively to your recollection of the testimony of the witnesses plus your evaluation of the exhibits or documentary evidence. You are not to be influenced in this exercise of judgment by the recollection of counsel or the recollection of the court on the facts. It is for you to say what the facts are from what you have heard from the witness stand.

"It is the responsibility of the court to instruct you as to the law which is applicable to the case and to assist in focusing your thinking on the real issues of the case. During the course of the trial, in ruling on questions of law raised by counsel, the court may have commented on pertinent evidence or testimony. These comments of the court on purely factual matters you will completely disregard. You may and should consider the argument made to you by counsel for the Government and counsel for the claimant.

"As has been stated, the Government contends that the alleged labeling represents and suggests that the Hoxsey treatment, being essentially the red and black tablets, is adequate and effective in the treatment of internal cancer in humans. It is for you to determine whether or not the alleged labeling makes such representations.

"In so determining, you are required to decide what their effect would be upon an ordinary consumer or purchaser under the circumstances attending the distribution of the pills. Thus you may consider what effect these various articles of literature would have upon the minds of persons suffering from internal cancer, who had come to the Hoxsey Clinic of Portage, Pennsylvania, in search of relief for their illness.

"In your deliberations and in arriving at your verdict, you will bear in mind that in an action of this kind the plaintiff has the burden of establishing his case by a preponderance of the credible evidence.

"In considering this case, you will examine all of the material evidence in order to determine its relevancy and the true state of facts. You will weigh all of the evidence in the case, so as to reconcile, if possible, such evidence as may have seeming or apparent conflicts. And in considering and weighing the evidence, you should use the same judgment, reason, common sense and general knowledge of men and affairs as you would in everyday life. In speaking of the burden of proof, I have referred to the requirement of preponderance of the evidence. This is a term which you no doubt will readily understand. It has been defined as that evidence which after a consideration of all the evidence is in the judgment of the jury entitled to a greater weight.

"Or stated in another way, the phrase, preponderance of the evidence, means that evidence which points to a certain conclusion appears to the jury to be more credible and probable than evidence to the contrary. It means such evidence as when weighed with that which opposes it has more convincing force and from which it results that the greater probability is in favor of the party upon whom the burden rests.

"In your consideration of this case, you must also take into account the credibility of the witnesses, of which, incidentally, you are the sole judges. With that the court has nothing to do.

"You may judge the credibility of a witness by the manner in which he gives his testimony, his demeanor upon the stand, the reasonableness or unreasonableness of his testimony, his means of knowledge as to any fact about which he testifies, his interest in the case, the feeling he may have for or against any of the parties, or any circumstances tending to shed light upon the truth or falsity of such testimony.

"And it is for you to say what weight you will give to the testimony of any and all witnesses. If you believe that any witness has wilfully sworn falsely to any material fact in this case, you are at liberty to disbelieve the testimony of that witness in whole or in part, or believe it in part and disbelieve it in part, taking into consideration all of the facts and circumstances of the case.

"If you are sympathetic or prejudiced in favor of or against any party, you should not allow it to influence you in your verdict.

"In arriving at your verdict you should be guided alone by the evidence and the law of the case, as the court has given it to you. You were asked at various times to refrain from reading newspaper articles or listening to broadcasts pertaining to this case. In deliberating upon your verdict, you

must consider only the evidence which you have heard here and the instructions on the law as given you by the court. Any other matter is not relevant.

"Let us turn to the issue of whether the alleged labeling is false or misleading as to an existing court decree, which pertains to a lawsuit in which the Hoxsey Cancer Clinic of Dallas, Texas, was involved. The discussion of this decree is found in the pamphlet, 'Hoxey Cancer Clinic, Dallas, Texas, Courtesy of Hoxsey Cancer Clinic, Portage, Pennsylvania, Specializing in the Treatment of Cancer, Precancerous and Chronic Diseases.' A copy of the decree which was in existence on the day of the seizure has been introduced in evidence for your examination.

"The Government's position is that the pamphlet indicates that claims as to the beneficial effect of the Hoxsey treatment could be made under certain circumstances, whereas in fact that decree prevents the making of such claims under any conditions.

"Looking at the same pamphlet again, the Government's further contention is that it is false and misleading with respect to an alleged survey made by Dr. Reimann, concerning cancer cases in Pennsylvania. This pamphlet contains certain statements made by a Dr. Miley, regarding what Dr. Reimann had done. There has been testimony that Dr. Miley did in fact make such statements, but Dr. Reimann testified he had not made any such survey and he was not of the opinion, as indicated, that X-ray and surgery did more harm than good in the treatment of cancer patients.

"It is contended by the claimant that the statement correctly quotes Dr. Miley. With respect to the statements made by Dr. Miley, as I recall the evidence, certain data had been collected but Dr. Reimann stated that the work had stopped and the data collected was insufficient to justify any conclusions. However, one is not justified in using a statement that is false or misleading merely because it is put forward as a quotation by some other person.

"The words, 'false,' and 'misleading,' are used in the statute in their ordinary sense and the statute is plain and direct. The word 'false' means untrue. The word 'misleading' is broader than the word false and includes any statement that may deceive or lead astray, even though it is not technically untrue. The term 'misleading' covers any word or phrase which by indirection and ambiguity may deceive and lead astray, and it covers half truths.

"In determining whether the alleged labeling is misleading, any words or phrases or articles which are ambiguous and liable to be misleading should be read by you in a manner which will accomplish the purpose of the statute. In other words, where two meanings are possible, you need not accept that interpretation which would result in the articles not being misbranded in that particular instance.

"On the question of whether the labeling falsely states that the Hoxsey cancer treatment is adequate and effective in the treatment of internal cancer in man, the evidence has been voluminous. The Government first brought before you physicians, pharmacologists, surgeons, and researchers in the field of cancer. In general, the consensus of these experts was that the Hoxsey cancer pills and the respective ingredients thereof were ineffective in the treatment of internal cancer. The testimony of the Government's experts was to the effect that at the present day modern science, in spite of efforts in research and investigation, recognizes that internal cancer may be adequately and effectively treated by surgical removal or by destruction by radiotherapy, including X-rays and radium and radioactive substances. As you will recall, the Government's witnesses said that progress had been made in the field of chemotherapy, being the treatment of cancer and diseases by means of drugs, but at the present time chemotherapy is not known to cure cancer, although in some instances, as with nitrogen mustard, it is known to have a palliative effect on certain types of cancers.

"The Government's expert witnesses were agreed that there was no evidence that potassium iodide, one of the ingredients of the Hoxsey cancer pills, was useful to alleviate or cure cancer; that since cancer was believed to be many diseases, no one drug would be effective in the treatment of all internal cancers.

"One of the Government's witnesses, I believe Dr. Goldzeher, testified as to the experiments he had conducted some years ago as to the effect of potassium on cancers in mice and humans. In general, he said his experiments had

proved that potassium did not help in the treatment of cancer but tended to worsen the condition.

"Opposed to the evidence of the Government's witnesses, claimant introduced the testimony of Dr. H. K. Hill and Dr. Eva Hill, both of whom had received the Hoxsey treatment. Both doctors stated that they had used potassium iodide in prescribing for patients. Dr. Max Gerson stated that he used potassium in his Clinic for the treatment of cancer in man. Dr. Allen, Medical Director of the Portage Clinic, and Dr. West, director of research at the Hoxsey Cancer Foundation in Dallas, Texas, also stated that they had observed improvement in patients suffering from cancer who had received the Hoxsey treatment.

"Witnesses having special professional qualifications have been permitted to express opinions as experts on the effectiveness of the pills here in question. They have been permitted to express opinions concerning the question in issue because they are experts, having special knowledge of a field in which ordinary persons lack experience or training. However, you are required to weigh and evaluate the testimony of an expert witness, whether called by the Government or by the claimant, exactly as you weigh and evaluate the testimony of any other witness, taking into account his interest in the case, his experience and training, his learning and standing in the profession, and the probability and reasonableness of the things to which he has testified.

"I charge you that the mere fact that some of the experts may have no personal experience with the use of the drugs in question does not nullify the weight to be attached to their testimony, if you find such persons were qualified in their fields and based their testimony on their general knowledge of medicine, that the drugs could perform the things claimed for them.

"In addition to the testimony of experts, the Government produced witnesses pertaining to various patients who had been treated at the Hoxsey Cancer Clinics. The Government's case centered on the seven patients who, as the Government contends, were set forth as having been treated effectively in the alleged labeling. It is the Government's position that these patients were not helped by the Hoxsey treatment and therefore the claims set forth in the literature are false and misleading.

"Reviewing the cases briefly, you will recall it is the Government's position that the Seago baby was suffering from a type of cancer which is known to regress spontaneously. In the case of Laura Bullock, now Morgan, I believe, Verne Haluska Kielbowick, and Glenn E. Freeman, the Government contends that they received adequate medical treatment before visiting the Hoxsey Clinic; that is, they received either surgery or X-ray or radium sufficient to effect their improvement and has produced medical testimony to this effect. In addition, the Government contends that two of the described persons, Mr. Dyer and Kathy Allison, died as a result of cancer while they were still being held out as cured. It is the Government's position that Richard Metzgar, who it says is described as a cured sufferer of Hodgkin's disease in the alleged labeling was not suffering from cancer in the first instance but an inflammation of the lymph. You will recall the testimony pertaining to the other case histories which was produced by the Government.

"In defense to the Government's contentions, the claimant contends that the Hoxsey black and red tablets are adequate and effective in the treatment of internal cancer in man. To support its case, the defense produced testimony pertaining to a number of patients, including some described in the alleged labeling. In general, this testimony was intended to show that the physical condition of the persons involved improved following their taking the Hoxsey treatment. Those testifying for the claimant included Mr. Glenn Freeman, who said that following surgical removal of a brain tumor his symptoms did not disappear until he began taking the Hoxsey treatment; Mr. Allison said that his daughter Kathy's pain was alleviated and her condition improved after she took the medicine although she eventually died. Similar testimony was given on behalf of the defense by Mrs. Bullock, now Morgan, and Mrs. Kielbowick. There was also testimony pertaining to the recovery of the Seago baby and Richard Metzgar. You are aware of the Government's contention with respect to these persons.

"Others, not described in the alleged labeling, indicated they also received benefit from the Hoxsey treatment as evidenced by improvement in their own physical condition after taking the Hoxsey preparation. You will recall the

testimony of those persons. The Government's contention primarily is that these persons had received adequate treatment, surgery or radiation, prior to their going to the Hoxsey Clinic or that they did not have cancer or that they have not improved by virtue of the Hoxsey treatment.

"This case is concerned with the Government's contention that the Hoxsey red and black pills are not adequate or effective in the treatment of internal cancer. Therefore, the treatment of external or skin cancer by the Hoxsey Cancer Clinics has no bearing whatever on this issue unless the cancer had spread to other parts of the body.

"Under the statute, drugs which are misbranded while held for sale after shipment in interstate commerce may be destroyed, regardless of the intention or motive of the persons distributing the drugs. The good faith of the Hoxsey Cancer Clinic or of the claimant or his sincere belief that the red and black pills are effective in treating internal cancer is not a defense to this action, if the pills were in fact misbranded. Nor would a base motive establish that the pills were misbranded. It should also be pointed out that the diagnostic abilities or lack thereof of the staff of the Hoxsey Cancer Clinic are not in question and any evidence bearing thereon cannot be considered by you as germane to the issue of misbranding.

"The question whether a person suffering from internal cancer has received adequate and effective treatment is essentially a medical question. Here the Hoxsey Cancer Clinic and the claimant have relied to a great extent on the testimony of certain patients or members of their families that following treatment by the Hoxsey method such persons improved in physical condition and that certain symptoms disappeared. It is your duty to evaluate such testimony, in the light of all of the evidence. In doing so, you should keep in mind the testimony as to the probable or likely effect on the person's physical condition of prior radiation or surgery where either had been administered, the ability of a lay person or one not skilled in medical science to correctly judge what treatment had caused his improvement, if there has been improvement, and the testimony relating to the nature of the disease of cancer as it may bear on this question. You should, of course, keep in mind the medical testimony offered by both parties.

"To summarize, the issues which you must decide in this case are:

"First, did the articles of literature referred to, which were found at the Hoxsey Clinic in Portage, Pennsylvania, accompany the red and black pills as labeling?

"If you decide that the literature did not constitute labeling, then your verdict should be for the claimant. If you determine that the literature was labeling which accompanied the pills, you should proceed to consider whether the labeling was false or misleading in any one of the following ways:

"A. Was the labeling false and misleading with respect to the terms of the court decree which has been described?

"B. Was the labeling false and misleading with respect to the alleged survey by Dr. Stanley Reimann?

"C. Was the labeling false and misleading with respect to the adequacy and effectiveness of the Hoxsey cancer treatment in the treatment of internal cancer in humans?

"If you find, by the fair weight or preponderance of the credible evidence, that the red and black pills were accompanied by labeling which was false or misleading in any one of the foregoing ways, your verdict should be for the United States.

"If you find that the labeling was not false or misleading in any of the aforesaid particulars, then your verdict should be in favor of the claimant.

"Your verdict should represent the conscientious, considered judgment of each juror. I think that you know that your verdict must be unanimous. When you retire to deliberate, consider the evidence, and each of you should discuss your views on the evidence freely and openly, in the light of reason and common sense, bearing in mind at all times that you would violate your sworn duty if you based your verdict on anything but the evidence heard in the courtroom and these instructions on the law.

"Members of the jury, there is one matter I failed to mention. I will mention it at this time.

"The Government has introduced evidence tending to show that Harry M. Hoxsey had some financial or proprietary interest in the Hoxsey Cancer Clinic of Portage, Pennsylvania.

"The relationship of Harry M. Hoxsey and the Hoxsey Cancer Clinic of Portage, Pennsylvania, is a question to be determined by the court and not by you, the members of the jury. I therefore instruct you to disregard any and all evidence tending to show whether Harry M. Hoxsey had a financial or proprietary interest or any interest in the Hoxsey Cancer Clinic at Portage, Pennsylvania.

"Certain requests for charge have been submitted to me by counsel for the Government. Those that I have approved I shall read to you.

"The points submitted by the Government which I approved read as follows:

"Written, printed and graphic material accompanies a drug if the printed matter is textually related to the drug and is used to explain the claimed merits of the drug to the public or is used to illustrate the purposes and conditions for which the drug is to be used.

"Another point that I approve is as follows:

"The drugs are misbranded if any one of the claims in the labeling is either false or misleading in any particular.

"Another point I approve reads as follows:

"In determining whether the labeling is false or misleading for any of the reasons claimed, you will take into account whether the labeling is likely to create a false or misleading impression as to the merits of the Hoxsey drugs on the mind of a person who reads the labeling.

"Another point which I approve reads as follows:

"You must completely disregard all cases presented by the claimant in this trial which relate to skin cancer or external cancer, unless you are satisfied that adequate proof has been presented by competent medical testimony that this cancer had spread into the body and thereafter it had been adequately and effectively treated by the Hoxsey method.

"All of those matters have been covered in my charge and the affirmance of the points submitted by the Government you will consider in what I have said about those points in my charge to you."

The jury returned a verdict for the Government, and the court entered a decree of condemnation on 11–16–56.

On 11–19–56, the claimant filed a motion for new trial and motion for judgment. The court, on 5–28–57, ruled as follows (152 F. Supp. 360):

MILLER, *District Judge:* "This is an action by the United States under the seizure and condemnation provisions of the Federal Food, Drug and Cosmetics Act, 21 U. S. C. A. § 301, et seq., for the destruction of a large quantity of red and black medicinal tablets and their labeling. It is alleged that the tablets were misbranded while held for sale at the premises of the Hoxsey Cancer Clinic at Portage, Pennsylvania, after having been shipped in interstate commerce. 21 U. S. C. A. § 334 (a). Upon a libel of information filed by the government, a warrant of seizure and monition was issued from this court, and on March 25, 1955, the tablets and certain pamphlets, magazines, and leaflets alleged to be the labeling were seized at the clinic. An answer to the libel has been filed on behalf of the Hoxsey Cancer Clinic and Dr. Newton C. Allen as claimants. The cause was tried before the court and a jury and after lengthy contested proceedings resulted in a verdict in favor of the United States. The claimants have filed a motion for judgment in accordance with their motion for a directed verdict and in the alternative a motion for a new trial. In the interim, execution of the order of condemnation entered on November 16, 1956, has been deferred.

"The Hoxsey Cancer Clinic is an institution at Portage, Pennsylvania, in the Western District of Pennsylvania, specializing in the treatment of cancer and cancerous diseases in humans by means of drugs and chemicals. It maintains a staff of physicians, nurses and administrative personnel. Persons from many parts of the nation suffering from cancer visit the clinic in hope of obtaining relief. These persons are not admitted as patients but visit the clinic for a

day or a few days at most during the course of which interviews and examinations are conducted. The examinations include blood tests, X-rays, rectal or vaginal inspection and other accepted medical procedures which do not involve surgery. Biopsies are rarely if ever performed. If as a result of the interviews and examinations superficial or skin cancer is diagnosed an escharotic compound—not the subject of this action—is prescribed as the chief means of treatment. If internal cancer is diagnosed, a prescription for the red or black tablets, depending on the nature of the cancer, is written out by the physician in charge. Other supportive medications, such as vitamins, are usually prescribed. The tablets and medications are received by the patient at the drug counter of the clinic and are taken home with him for consumption according to given directions. The basic fee for the cancer treatment, including examinations and medications, is $400. In addition laboratory fees of from $5 to $18 and X-ray fees at $10 per picture are charged. If the patient acquires additional tablets no further charge is made except for laboratory or X-ray services. The tablets involved in this action, concededly 'drugs' within the meaning of the Food and Drugs Act, were prepared by a Michigan pharmaceutical house at a cost of less than $2 a thousand and were transported in interstate commerce. The red tablets are composed of potassium iodide, red clover tops, stillingia root, berberis root, poke root, buckthorn bark and pepsin; the black tablets of potassium iodide, licorice, red clover tops, burdock root, stillingia, berberis root, poke root, cascara sagrada, prickley [sic] ash bark and buckthorn bark. The tablets are the essential part of the Hoxsey treatment for cancer and potassium iodide is considered by claimants the chief curative component.

"The clinic began its operations in February, 1955, in an atmosphere of great local interest. When the seizure was effected on March 25, 1955, patients were being received for examination and treatment. The medications, the subject of this action, were then located in the drug and sterilization rooms at the rear of the clinic in their original containers from which they were eventually to be transferred to small envelopes for distribution to patients. Copies of the leaflets and printed matter described above in the caption and seized with the tablets were found on a table in the foyer of the clinic which adjoined a waiting room used by patients and persons visiting the clinic. The bundled copies of the 'Defender' magazine were seized in one of the rear rooms. The government, centering its attack only on Hoxsey medications used in the treatment of internal cancer, contends that the leaflets and printed matter caused the red and black tablets to be misbranded in three particulars: by making false or misleading representations with respect to the adequacy or effectiveness of the tablets in the mitigation and treatment of internal cancer; with respect to the terms of an existing court decree prohibiting entities not parties to this action from making such labeling claims for similar drugs distributed in interstate commerce; with respect to a survey allegedly discounting the effectiveness of X-rays, radium and surgery in treating cancer patients. The issues submitted to the jury were whether the printed matter and leaflets constituted 'labeling' within the meaning of the Food and Drugs Act and if so, whether the labeling was false or misleading in any of those three particulars.

THE MOTION FOR JUDGMENT

"Under § 304 (a) of the Food and Drugs Act, 21 U. S. C. A. § 334 (a), any article of drug that is misbranded while held for sale after shipment in interstate commerce is subject to federal seizure and condemnations procedures in accordance with the act. Under § 502, 21 U. S. C. A. § 352, a drug is misbranded if its labeling is false or misleading in any particular, and labeling is defined in § 201, 21 U. S. C. A. § 321, as meaning all labels and other written, printed or graphic matter upon the article or its container or 'accompanying such article.' In their first point in support of the motion for judgment, claimants present the contention that the leaflets and printed matter involved in this action were not labeling in the statutory sense. In *Kordell* v. *United States*, 1948, 335 U. S. 345, 350, the Supreme Court said:

> One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.

That case and *United States* v. *Urbuteit*, 1948, 335 U. S. 355, establish that if the written, printed or graphic matter is used in the distribution or sale of a drug which has been shipped in commerce to explain the drug's use or usefulness, it may be considered labeling in a functional sense, even though there is a separation between the article and the printing. It is unnecessary to determine here how wide the separation may be before written, printed or graphic matter ceases to 'accompany' the drug article. In the present instance, the literature was prominently displayed and available for reading by or distribution to patients or other persons at the very place where the Hoxsey medications were distributed. In addition, undisputed evidence demonstrated that the literature was sometimes mailed to patients. Under such circumstances, this court will not permit the yards of distance between the clinic's waiting room and the drug rooms or the intervening plaster walls to be the measurement of the application of the federal regulatory law. The pamphlet entitled, 'Hoxsey Cancer Clinic' [1] states that its purpose is to acquaint the public with the clinic and its method of treating cancer 'in terms the average layman can understand.' It contains the statement 'we do feel that we have the most advanced and efficient method of treating cancer today'—a method not including X-ray, surgery or radiation. It describes the procedure to be followed by prospective patients desiring consultations or treatment. The leaflet, 'Procedure and Information' [2] lists the fees charged by the clinic for the cancer treatment and laboratory and X-ray services. The article from 'Man's Magazine' entitled, 'I Conquered Cancer' [3] details what appear to be a disinterested person's statement and report on the case histories of seven persons who were, the article indicated, treated successfully by the Hoxsey method after other treatment had failed. It includes a report on Mrs. Verne Kielbowick, sister of John Haluska, a former member of the Pennsylvania legislature and Administrator of the Portage Clinic. Mrs. Kielbowick attributed the recovery of her health to the Hoxsey remedy and is quoted as saying:

> If anybody doubts that Hoxsey cures cancer, let him come to Patton and talk to the Haluskas.

The pamphlet, 'Findings of Doctors' [4] contains the statement:

> [O]ur investigation has demonstrated to our satisfaction that the Hoxsey Cancer Clinic at Dallas, Texas, is successfully treating pathologically proven cases of cancer, both internal and external, without use of surgery, radium, or X-ray.

The 'Defender' magazine [5] includes a reproduction of a speech by former Senator Haluska to the Pennsylvania Senate in which he referred repeatedly to cures of cancer victims by the use of the Hoxsey treatment. It will be seen therefore that the materials consistently extolled the merits of the Hoxsey drugs in terms which the average layman would understand and which would be appealing to persons afflicted with the disease of cancer. Although modestly disclaiming that the drugs were a 'cure-all' and putting the case for the tablets in terms of 'you be the judge,' the literature nevertheless explained what the drugs were for and implied that they were effective and superior medicines. The facts were clear and great liberality was shown in permitting the jury to pass upon the contention that the literature was not labeling.

"In their second point, claimants argue that the drug articles in question were not 'held for sale after shipment in interstate commerce' within the meaning of § 304 (a), supra. However, they concede that the red and black tablets were shipped in interstate commerce and were the 'essential part' of the Hoxsey treatment for internal cancer in humans and that in the ordinary case a charge of $400 was made for a complete course of treatment exclusive of laboratory fees and X-ray charges. Upon those undisputed facts it would seem clear that the articles were held for sale. Claimants

[1] Government Exhibit 24.
[2] Government Exhibit 41.
[3] Government Exhibit 42.
[4] Government Exhibit 43.
[5] Government Exhibit 39.

urge nevertheless that the drugs were intended, not for sale in the statutory sense, but for prescription by physicians in the pursuit of a local practice of medicine with which the act was not intended to deal and with which this court could not interfere. In this contention they are wrong.

"The overriding purpose of the federal Food and Drugs Law was to protect the lives and health of the public by keeping misbranded, adulterated and impure foods and drugs out of the channels of interstate commerce. The coverage of the statute was enlarged by the Act of 1938 to every article that had gone through interstate commerce until it finally reached the ultimate consumer by making its prohibitions applicable to such articles 'while held for sale after shipment in interstate commerce.' *United States* v. *Sullivan*, 1947, 332 U. S. 689, 697. It may be that physicians are not understood as holding for sale the drugs which they may administer or prescribe in connection with their treatment of patients. But the potentiality of harm to the public from misbranded drugs is not less because the intervening agency of distribution may be a physician rather than a layman.[6] The terms 'while held for sale' have been given an expansive rather than a technical construction, *Kocmond* v. *United States*, 7 Cir., 1952, 200 F. 2d 370, cert. den. 345 U. S. 924; *United States* v. *1800.2625 Wine Gallons*, 1954, D. C. W. D. Mo., 121 F. Supp. 735, and must be deemed to include the operations of the claimants in distributing their drug tablets at the Hoxsey Cancer Clinic. It is not the holding for sale in a technical legal sense which gives rise to the federal jurisdiction in cases arising under § 304 (a) but the fact that the channels of commerce have been used. *United States* v. *1800.2625 Wine Gallons*, supra. Since interstate transportation has been admitted, the ban of the section applies to the tablets here involved regardless of the claims of the Hoxsey Cancer Clinic and Dr. Newton C. Allen, its medical director. If forfeiture works any interference with claimants' practice of medicine it is a mere incident of their violation of the law in making representations concerning their drugs which the jury found were unwarranted, false or misleading.[6]

"The only other point which is urged in support of the motion for judgment may be dismissed without much discussion. Claimants say that the proper standard to be applied in determining whether there was a misbranding of the Hoxsey tablets while they were 'held for sale' is to be found in subsection (k) of § 301 of the act, 21 U. S. C. A. § 331 (k), which prohibits:

> The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Claimants construe that language very narrowly and say that the government failed to sustain its burden of proof because it did not show that anything affirmative was done to the drugs themselves, which remained undisturbed in their original containers. Section 301 sets forth 'Prohibited Acts' and § 303, 21 U. S. C. A. § 333 makes violation of the provisions of § 301 a criminal offense. Section 301 had no real application in this civil proceeding for condemnation of misbranded drugs under § 304 (a). In any event, the bringing into association of the alleged labeling and the drugs was a sufficient act 'with respect to' the drugs which in this case rendered them misbranded.

THE MOTION FOR A NEW TRIAL

"Although more than twenty overlapping reasons have been assigned in the motion for a new trial, all except those set forth under points 4, 6, 8, 15 and 17 were expressly abandoned by counsel for claimants on argument. Points 4 and 6 deal with asserted errors in the admission of evidence; the remaining points present alleged errors in the charge to the jury. The objections to the evidence are dealt with first.

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[6] When Congress intended to exempt licensed practitioners from the operation of the Act, it spoke plainly enough. See § 503 (b) (2), 21 U. S. C. A. 353 (b) (2).

"The testimony of Shanley and Gulledge, federal food and drug agents. Shanley at the Portage Clinic and Gulledge at the Dallas Clinic, posing as cancer patients, were examined in the customary manner, told they had cancer and given a supply of the Hoxsey medication to take home and consume. Neither had cancer. The testimony was offered to show the similarity of procedures at the two clinics and the inadequacy of the procedures. The evidence, with other evidence in the case, was relevant as bearing on the relationship between the two clinics and on the question whether there was privity between the Portage Clinic and the Dallas Clinic and Harry N. [sic] Hoxsey, against whom and the Dallas Clinic a prior injunctive decree had been entered. When the application of the doctrine of collateral estoppel was exclusively reserved to the court at the end of the case by withdrawing the question of privity from the jury, the testimony of Shanley and Gulledge, say the claimants, stuck out like a sore thumb. In a case of long duration involving contested issues of legal and factual complexity, it was impossible to foresee the exact boundaries of the case to be submitted. The members of the jury were told they were not to concern themselves with the question of privity; they were told that the question of misbranding did not depend on the intention or motives of those distributing the drugs and that the diagnostic abilities of the staff of the clinic were not in question. Under the circumstances, this was sufficient.

"The evidence revealing the deaths of Crescens Klemmer (sic), James Barger and Nicolei Lupanov (sic). These persons were cancer victims who were treated according to the Hoxsey method. The account of their medical history, illness and death by relatives and physicians was pertinent in showing whether they had been thus effectively treated for their disease. It was not suggested to the jury that their deaths were conclusive on the question. Similar testimony was admitted in *United States* v. *Kaadt*, 7 Cir., 1948, 171 F. 2d 600, 603, a case involving a claimed cure for diabetes.

"The cross-examination of Doctor West. On direct examination, West (employed as director of research at the Hoxsey institution in Dallas, Texas) supported the claim of merit for potassium iodide, the principal ingredient of the Hoxsey medicines, which, according to his statement, had produced good results in a large number of cases by a process of strangulation or asphyxiation of abnormal tissue. The testimony of the government's expert medical witnesses and researchers had indicated that potassium iodide was either of no effect or harmful in the treatment of cancer. Without first interrogating West as to a past criminal record, government counsel placed in evidence a certified copy of a complaint and record [7] revealing that on May 14, 1953, the witness pleaded guilty to a charge of practicing medicine without a license in the City of Los Angeles. This procedure did not amount to a reversible error. 3 Wigmore on Evidence (3d Ed.) § 980. In addition it was shown through official records of the State of New York [8] that West had been denied permission in 1951 to practice medicine in New York because of insufficient training. Both matters affected the qualifications of the witness, which were directly in issue, and were properly received.

"In their motion for a new trial, claimants renew their argument relating to the holding for sale of the tablets in question, this time contending that whether the tablets were held for sale within the meaning of the statute should have been determined by the jury and not by the court as a matter of law. The court has adverted to and discussed the 'held for sale' requirement of § 304 (a) extensively and has pointed out that there was no substantial dispute as to the important factors for determining whether there was a statutory holding for sale: a substantial charge was made for the course of treatment by the Hoxsey method and the treatment included prescription of the tablets as its essential part. The tablets at the time of the seizure had not yet reached the hands of the ultimate consumers and were therefore held for sale. *Kocmond* v. *United States, supra*, 200 F. 2d at 373. Nothing remained for the jury.

"Claimants take the view that the court erred in telling the jury to consider in determining whether the Hoxsey medications were misbranded the impression which the various articles of literature would have upon the minds

[7] Government Exhibit 210.
[8] Government Exhibit 209.

of victims of internal cancer who came to the clinic as patients. Although exception was taken to this point in the charge, claimants did not either before or afterwards suggest to the court what other standard they thought proper. However, the given instruction was appropriate. Claimants designedly or at least willingly made the labeling available for the use of unfortunate persons who were afflicted with cancer or who thought they were and who had come to the clinic for help. The literature would naturally appeal to those persons as it was undoubtedly intended to. They were the persons upon whom it would have its greatest effect because they were likely to be less critical, and less apt to question the representations by laymen and others reported in the leaflets. It is therefore only fitting that the truth or falsity of the literature or its misleading nature be measured by its significance to them and not to persons who for one reason or another would be likely to form a more critical judgment. In this conclusion, the court is supported by plentiful authority. *United States* v. *Vitamin Industries, Inc.*, 1955, D. C. Neb., 130 F. Supp. 755, 767; *United States* v. *23 Articles*, 2 Cir., 1951, 192 F. 2d 308, 310; *United States* v. *Kaadt*, supra, 171 F. 2d at 603; *United States* v. *Hoxsey Cancer Clinic*, 5 Cir., 1952, 198 F. 2d 273, 276, cert. den. 344 U. S. 928, rehearing den. 345 U. S. 914.

"The next argument is that it was a reversible error to tell the jury that the question whether one suffering from internal cancer has received adequate and effective treatment was 'essentially a medical question.' A new trial will not be awarded for this reason. Claimants argue that the statement required the jury to give more credence to the doctors who testified than to the patients themselves who were called by claimants to testify as to their physical conditions before and after receiving the Hoxsey treatment. Assuming this would have been improper, claimants' assignment is merely an instance of the long discountenanced practice of leveling attacks at an isolated portion of the charge without regard to what was said before and after. The issues to be decided were made clear to a jury which after many weeks of trial was well aware of the contentions and proofs of both parties and equipped with more knowledge about the disease of cancer than most laymen would ever acquire. They were told to evaluate claimants' evidence in light of all the testimony, including that of the doctors offered on both sides. There is no just cause for complaint.

"There remains to be considered only the assignments raising the propriety of the submission to the jury of certain statements in the printed matter as separate instances of misbranding. The first of these[9] set forth a summary of a report by Dr. George Miley, described as medical director of the Gotham Hospital, New York, and having impressive qualifications, to a Congressional Committee relating to a survey of cancer patients in Pennsylvania allegedly conducted by Dr. Stanley Reimann. The substance of the report, as summarized, was that Reimann's survey 'over a long period of time' had established that cancer patients fared better if they did not receive treatment by radium, X-ray or ordinary surgery. All of this, including the making of such a survey, was denied by Dr. Reimann who was called as a witness for the government and who also testified that he had notified the committee that Miley's report was inaccurate. The literature did not note his protest. See 21 U. S. C. A. § 321 (n). Claimants urge that no instance of misbranding was shown because the report had in fact been made as set forth in the literature. However, at least by indirection the printed matter created an impression that it was a fact that such a survey had been made and that the survey justified the conclusions asserted. It would naturally tend to have greater effect upon a susceptible reader not only because the author of the report was a member of the medical profession but also because of the dignity of the forum to which the report was addressed. On the evidence the jury could have found that the facts implied in claimants' literature were untrue. It is not possible for claimants to escape responsibility for those implications now. Drawn as they were, the statements made a more persuasive appeal to cancer sufferers than if the representations implied had been made directly by claimants alone and for that reason, it has been said, they are not less but more obnoxious to the law. *United States* v. *John J. Fulton Co.*, 9 Cir., 1929, 33 F. 2d 506; cf. *United States* v. *David Roberts Veterinary Co. Inc.*, 7 Cir., 1939, 104 F. 2d 785, 789; cf. *Moretrench Corporation* v. *Federal Trade*

[9] Government Exhibit 24, p. 8.

Commission, 2 Cir., 1942, 127 F. 2d 792, 795. In submitting the issue to the jury, the court merely followed the explicit canon of construction of the act which the Supreme Court long ago set forth in *United States* v. *95 Barrels of Vinegar*, 265 U. S. 438, 442:

> The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambigious [sic] and liable to mislead should be read favorably to the accomplishment of the purpose of the act. . . .

"The second challenged statement is found in the printed matter [10] under the heading 'Court Rulings.' In the text appears a discussion of proceedings instituted by the United States against the Hoxsey Cancer Clinic of Dallas, Texas, and Harry N. [sic] Hoxsey in the District Court for the Northern District of Texas. Then follows the statement that the District Court in obedience to the mandate of the Court of Appeals (198 F. 2d 273), on June 29, 1953, entered a decree of injunction restraining the distribution in interstate commerce of the Hoxsey medications containing labeling representing that the substances were effective or of value in the treatment of cancer *'without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations.'* What the printed matter failed to mention was that in mandamus proceedings instituted against the District Judge, the Court of Appeals determined that its mandate had not been obeyed and required the lower court to expunge from its decree the qualifying phrase quoted above. (207 F. 2d 567.) This was done on October 26, 1953.[11] Claimants do not deny the false or misleading character of the representations made in the literature but simply suggest that the omissions were not material. This contention boils down to an argument that the misrepresentations could not possibly be 'labeling'—i. e., printed matter accompanying the drug in the sense of explaining its use or usefulness. *Kordel v. United States*, *supra*. The Court of Appeals for the Fifth Circuit after carefully weighing the evidence in the case had actually concluded as a fact that the drugs, substantially identical to those involved here, were of no value in the treatment of cancer, but the literature created the impression that the Court had taken an indecisive stand. It is the view of this court that the considered judgment of such a tribunal of the United States with respect to the merits of the very substances in question would necessarily be of significance to any person interested enough to read about the Hoxsey remedy and particularly to those who were confronted with the choice of accepting or declining the Hoxsey treatment. By implying that a court of the United States had sanctioned the making of claims of effectiveness for the drugs, the literature gave the impression that the Hoxsey remedy in fact had merit and in this sense directly explained its usefulness. At most, the question is one upon which reasonable persons could differ.

"The vital issue in this case was the efficacy of the Hoxsey treatment for internal cancer in humans. No claim is made that the question of the adequacy and effectiveness of the tablets was improperly submitted to the jury. Claimants were given the fullest opportunity to state their case for the drugs but their evidence was rejected by the jury. The court is not called upon in this opinion to discuss the sufficiency of the government's expert and lay testimony showing that the drugs were without merit in the treatment of cancer and observes only that the verdict of the jury is supported by persuasive and overwhelming evidence. The Hoxsey medications have again been weighed and found wanting.

"The motions for judgment and a new trial will be denied."

On 7–9–57, the claimant filed a second motion for a new trial, alleging that improper and prejudicial matter was communicated to a member of the jury

[10] Government Exhibit 24, pp. 5–8.

[11] Government Exhibit 121.

prior to the submission of the case for the jury's consideration; that the case was discussed before the juror; and that there was misconduct on the part of the juror in that the matter was not called to the attention of the court. The claimant filed notice of appeal on 7–16–57.

On 8–23–57, the district court entered a decision with respect to the claimant's second motion for a new trial, as follows:

MILLER, *District Judge:* "On May 28, 1957, an opinion and order was filed denying the claimant's motion for new trial. The claimant on July 9, 1957, pursuant to Rule 59 and Rule 60 of the Federal Rules of Civil Procedure, filed a second motion for a new trial and on July 16, 1957, filed notice of appeal. The filing of the notice of appeal vests jurisdiction over the cause appealed in the Court of Appeals and this court has no power to take other action affecting the cause without permission of the Court of Appeals, except insofar as jurisdiction is expressly reserved in the district court by statute or the Federal Rules of Civil Procedure. See *In the Matter of Federal Facilities Realty Trust Company, et al., Appellant vs. Jacob Kulp, et al., Appellees,* 227 F. 2d 651 (7 Cir.)."

On 8–29–57, the claimant filed a motion to remand the cause to the trial court, so that a hearing on the second motion for a new trial might be had in the district court. The United States Court of Appeals for the Third Circuit, after a hearing, entered an order denying the motion on 9–4–57.

On 9–5–57, the claimant filed a motion for amplification of the order, denying the motion to remand, and on 9–10–57, filed a motion to strike the Defender Magazine as part of the record on appeal. These motions were denied by the court of appeals on 9–23–57.

On 10–4–57, the claimant and the Government filed an agreement to dismiss the appeal; the court of appeals entered an order on 10–7–57 dismissing the appeal, the costs to be assessed against the appellant.

On 10–22–57, the district court entered an order directing the marshal to destroy the tablets and the accompanying labeling.

5213. Digitalis tablets. (F. D. C. No. 39515. S. No. 46–899 M.)

QUANTITY: 1 btl. containing 14,000 tablets at Philadelphia, Pa.

SHIPPED: 8–30–56, from Camden, N. J., by Olmstead Labs.

RESULTS OF INVESTIGATION: Examination of the article showed that it had a potency of 1.06 grs. of U. S. P. digitalis per tablet.

LIBELED: 10–10–56, E. Dist. Pa.

CHARGE: 502 (a)—the statement on the label of the article, when shipped, namely, "Tablets Digitalis U. S. P. 1½ Grains," was false and misleading.

DISPOSITION: 11–5–56. Default—destruction.

5214. Manganese dioxide. (F. D. C. No. 39069. S. Nos. 41–358/60 M.)

QUANTITY: 1 20-lb. drum, 10 4,000-tablet btls., 1 2,000-tablet btl., and 7 1,000-tablet btls. at Buffalo, N. Y., in possession of Jopp Pharmacal Co., Inc.

SHIPPED: 8–1–55, from Phillipsburg, N. J.

LABEL IN PART: (Drum) "Manganese Dioxide, Technical * * * Powder * * * For Manufacturing Use Only": (btl.) "Jopp's Tablets Manganese Dioxide C. P. (MnO2) Each Capsule contains Manganese Dioxide 5 grs. combined with 2½ grs. Sodium Bicarbonate and Aromatics."

RESULTS OF INVESTIGATION: The article had been shipped in bulk in powdered form, and upon arrival at Buffalo, N. Y., the consignee tableted and repack-

aged the drug into bottles labeled as above. The consignee also encapsulated some of the bulk powder.

LIBELED: 5-9-56, W. Dist. N. Y.

CHARGE: 502 (a)—the label of the article, while held for sale, contained the statements, "Highly recommended in Diabetes treatment" and "Manganese Dioxide C. P.," which were false and misleading since the article was not an adequate and effective treatment for diabetes and the article was a technical grade of manganese dioxide.

DISPOSITION: 8-28-56. Default—destruction.

5215. Al-Co-Way Tablets. (F. D. C. No. 38702. S. No. 28-045 M.)

QUANTITY: 66 btls. at Columbus, Ga., in possession of Ernest C. Fokes, t/a Primary Products Co.

SHIPPED: During April 1955, from New York, N. Y.

LABEL IN PART: (Btl.) "50 Al-Co-Way Tablets Caffeine Citrate And Thiamin Hydrochloride To Discourage Excessive Use of Alcoholic Beverages * * * Dist. By Primary Products Co. Columbus, Ga."

RESULTS OF INVESTIGATION: The article was shipped in bulk to Columbus, Ga., and after its receipt it was repackaged and relabeled by the consignee.

LIBELED: On or about 11-28-55, M. Dist. Ga.; libel amended on or about 2-15-56.

CHARGE: 502 (a)—the statement on the label of the article, while held for sale, namely, "Al-Co-Way Tablets * * * To Discourage Excessive Use Of Alcoholic Beverages" was false and misleading since the statement represented and suggested that the article was an adequate and effective treatment for alcoholism, whereas the article was not an adequate and effective treatment for alcoholism.

DISPOSITION: Ernest C. Fokes, as owner of the article, filed an answer denying that the article was misbranded. The Government served written interrogatories upon the owner, and on 4-14-56, the owner filed answers to some interrogatories and objections to the remainder of the interrogatories. A hearing was held on the objections, and on 8-20-56, the court ordered that all objections be sustained, with the exception of the objections relating to two of the interrogatories. The case was tried before the court and jury on 9-12-56, and at the conclusion of the trial, the jury returned a verdict for the Government. On 12-28-56, the court entered a decree ordering the destruction of the article.

5216. Prof. Black's Honey and Tar Red Pepper and Rum. (F. D. C. No. 39673. S. No. 47-887 M.)

QUANTITY: 38 6-oz. btls. at Sussex, N. J.

SHIPPED: 10-4-56, from Middletown, N. Y., by O. C. Prior-King.

LABEL IN PART: (Btl.) "Prof. Black's Honey and Tar Red Pepper and Rum."

LIBELED: 11-8-56, Dist. N. J.

CHARGE: 502 (a)—the bottle label of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for overcoming colds, coughs, sore throat, quinsy, diphtheria, and all throat and lung complaints, and for preventing pneumonia, pleurisy, and consumption.

The libel alleged also that another article, imitation vanilla flavor, was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on food.

DISPOSITION: 12–11–56. Default—destruction.

5217. N. S. T. skin treatment. (F. D. C. No. 39658. S. No. 56–372 M.)

QUANTITY: 49 4-oz. btls. at Fargo, N. Dak.

SHIPPED: 5–10–56, from Brainerd, Minn., by Northland Pharmacal Co.

LABEL IN PART: (Btl.) "'N. S. T.' The Universal Skin Treatment Fortified with Lanolin * * * CONTAINS: Glycerin, Boric Acid, and assorted oils & herbs."

RESULTS OF INVESTIGATION: Analysis showed that the article contained borates, tragacanth, glycerin, alcohol, oil of cajeput, and oil of eucalyptol.

LIBELED: On or about 11–7–56, Dist. N. Dak.

CHARGE: 502 (a)—the label of the article, when shipped, contained false and misleading representations that the article was "The Universal Skin Treatment" and was an adequate and effective treatment for eczema, dermatitis, and acne; and 502 (e) (2)—the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient contained therein since the words "assorted oils & herbs" were not the common or usual name of any substance.

DISPOSITION: 12–7–56. Consent—destruction.

5218. Yerba maté. (F. D. C. No. 39308. S. No. 46–779 M.)

QUANTITY: 30 lbs. at Atlantic City, N. J., in possession of J. Gordon & Co.

SHIPPED: 5–21–56, from New York, N. Y.

LABEL IN PART: (Box) "Yerba Mate Toasted Paraguay Tea."

ACCOMPANYING LABELING: Leaflets entitled "J. Gordon's Yerba Tea (Brazilian Tea)."

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed locally for J. Gordon & Co.

LIBELED: On or about 7–31–56, Dist. N. J.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective in the treatment of rheumatism, neuritis, kidney trouble, excess uric acid, gout, neuralgia, diabetes, and nervous ailments, and that it would increase physical strength.

DISPOSITION: 9–12–56. Default—destruction.

5219. Hot-R-Cold Mask and Hot-R-Cold Pak. (F. D. C. No. 38941. S. Nos. 35–911/12 M.)

QUANTITY: 118 devices at Chicago, Ill.

SHIPPED: Between 10–31–55 and 11–22–55, from Quincy, Mass., by Hot-R-Cold Pak, Inc.

LABELING: (Ctn.) "Hot-R-Cold Mask * * * Hot-R-Cold Pak" and "Combination Hot Water Bottle and Ice Pak * * * Hot-R-Cold Pak."

RESULTS OF INVESTIGATION: The *Hot-R-Cold Mask* device consisted of a pliable plastic transparent face mask made so as to cover the upper part of the face with openings for the eyes, and with plastic straps which could be fastened around the back of the head. The mask portion was constructed with an inner chamber which contained a blue-colored liquid.

The *Hot-R-Cold Pak* device consisted of a pliable transparent plastic container in the shape of a rectangle measuring approximately 11 inches by 7

inches which was subdivided into 2½ inch by 7 inch rectangular compartments. Each compartment was filled with a blue-colored liquid.

CHARGE: 502 (a)—the labeling of the devices, when shipped, contained false and misleading representations that the *Hot-R-Cold Mask* provided an adequate and effective treatment for sinus conditions and that the *Hot-R-Cold Pak* provided an adequate and effective treatment for stiff joints, earaches, sore throat, and swellings.

DISPOSITION: 6–15–56. Default—articles delivered to the Food and Drug Administration.

5220. Ear stopples. (F. D. C. No. 39289. S. No. 47–149 M.)

QUANTITY: 1 case of 100 12-tube ctns. and 1 case of 150 12-tube ctns. at Philadelphia, Pa.

SHIPPED: 5–24–56, from Los Angeles, Calif., by Healthways of Hollywood.

LABEL IN PART: (Ctn.) "Healthways The Ideal Ear Stopple Protects your ears from Water & Noise. * * * Recommended by Swim Coaches & Medical Authorities to help prevent Ear Disorders & Polio"; (tube) "Health-ways The Ideal Ear Stopple Moisten * * * Small."

RESULTS OF INVESTIGATION: The device consisted of 2 rubber stoppers designed so as to fit easily into each ear.

LIBELED: 7–2–56, E. Dist. Pa.

CHARGE: 502 (a)—the label of the article, when shipped, contained false and misleading representations that the device was effective for preventing ear disorders and polio.

DISPOSITION: 7–5–56. Consent— claimed by Healthways, Inc., and relabeled.

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PRODUCTS

[1] (5215) Seizure contested.
[2] (5202) Injunction issued. Contains orders of the court.
[3] (5212) Seizure contested. Contains opinions of the court and instructions to the jury.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5215) Seizure contested.
[2] (5202) Injunction issued. Contains orders of the court.
[3] (5212) Seizure contested. Contains opinions of the court and instructions to the jury.
[4] (5203) Prosecution contested.

[2] (5202) Injunction issued. Contains orders of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1958

D. D. N. J., F. D. C. 5221–5240 Issued August 1958

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5221–5240

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They relate to drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) criminal proceedings which were terminated with a plea of guilty or nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *August 22, 1958.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see No. 5226; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5226; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5226.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5221–5240

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of chlortetracycline or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5221. Methyltestosterone tablets and Vita-40 tablets. (F. D. C. No. 38514. S. Nos. 39–578 L, 40–262 L, 74–711 L, 11–082 M.)

INDICTMENT RETURNED: 4–4–56, S. Dist. Calif., against Vita Pharmacals, Inc., Los Angeles, Calif., and Floyd L. Clemens, president.

ALLEGED VIOLATION: The indictment alleged that a quantity of methyltestosterone had been shipped on or about 8–19–54 from New York to California, where it was fabricated into tablets and delivered to the defendants; that following such delivery and while such methyltestosterone in tablet form was being held for sale after shipment in interstate commerce, the defendants caused a quantity of the article in tablet form to be dispensed on 9–18–54 in a box without a prescription and an additional quantity of the article in tablet form to be repacked into boxes and accompanied by certain labeling in the period of 9–15–54 to 9–22–54; that the defendants' act of causing the dispensing of a quantity of the article in tablet form was an act done contrary to the provisions of 503 (b) (1), which resulted in the article being misbranded while

held for sale; and that the defendants' act of causing a quantity of the article in tablet form to be accompanied by certain labeling resulted in such quantity of the article being misbranded as described below.

The indictment alleged also that the defendants, on 7–24–54 and 8–4–54, caused the introduction into interstate commerce, for delivery to Phoenix, Ariz., and Houston, Tex., of *Vita–40 tablets*, misbranded as described below.

LABEL IN PART: (Box) "VITA HORMONES 50 Tablets Each Tablet Contains 10 Mg. Methyltestosterone SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are presribed or recommended by a physician for palliative relief of such symptoms. Distributed by VITA PHARMACALS, INC. * * * It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician. CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed" and "VITA–40 TABLETS * * * Distributed by VITA PHARMACAL COMPANY."

ACCOMPANYING LABELING: Leaflets entitled "Price List of New Male Hormone Tablets" and "The Evidence"; placard entitled "Doctor Says Hormones Key to Rejuvenation"; leaflets containing a reproduction of an article entitled "Hormone Dosages Safe, Doctors Told" from the Los Angeles Times; folders containing a reproduction of an article entitled "Hormones For Men" from the American Weekly.

CHARGE: *Methyltestosterone tablets* with the aforesaid accompanying labeling. 502 (a)—this labeling contained false and misleading representations that the article was an adequate and effective treatment for providing renewed vigor, endurance, strength, and vitality in men over 40, replenishing male vigor in men over 40, replenishing power vitiated by age and the stress and strain of modern living, relieving varied symptoms of mental and bodily stress in persons of later years, overcoming imbalance in the glandular system resulting in insomnia and other nervous symptoms, overcoming the signs of the "male climacteric," overcoming fatigue, nervousness, and irritability in old men, overcoming excessive perspiration and progressive numbness of the body, making old persons younger and healthier, and making old persons more active physically and mentally; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; 502 (f) (2)—the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for

the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling was couched was inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of cancer of the prostate gland or may cause sterility; 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since each tablet of the article contained 10 mg. of methyltestosterone (a male hormone), and the use of a drug containing 10 mg. of methyltestosterone in each tablet with the frequency and duration prescribed, recommended, and suggested, to wit, as directed on the box label, "One tablet upon arising before breakfast or one tablet shortly before retiring . . . The maintenance dosage can be extended from three to six months, under supervision of a physician," would be dangerous to health since such use of the drug may result in sterility and such use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth; and 503 (b) (4)—the article was a drug subject to 503 (b) (1) (B), and its label, prior to dispensing, failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Vita–40 tablets. 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for providing pep, vitality, new vigor, new life, new hope, and renewed vitality in men over 40 years of age, and for overcoming male sexual weakness, especially in men over 40 years of age; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

PLEA: Guilty.

DISPOSITION: 10–8–56. Corporation—$1,000 fine; individual—$1,000 fine and placed on probation for 5 years.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5222. Pega Palo. (F. D. C. No. 39892. S. No. 60–028 M.)

QUANTITY: 600 labeled pkgs. and an unknown quantity of bulk vine at Chicago, Ill., in possession of A–1 Import Co.

SHIPPED: During December 1956 and January 1957, from the Dominican Republic.

LABEL IN PART: (Pkg.) "Pega Palo Vine, Chicago, Illinois."

ACCOMPANYING LABELING: Sheets reading, in part, "Gentlemen * * * Description: Product is an aphrodisiac * * * Sincerely Yours: Harold Baum: A–1 Import Co." and "Detailed Information as to the use & Cost of Pega Palo Vines: * * * Very Truly Yours Harold Baum: A–1 Import Co."

LIBELED: 3–8–57, N. Dist. Ill.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use of the article as an aphrodisiac; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 3–29–57. Default—delivered to the Food and Drug Administration.

5223. Pega Palo. (F. D. C. No. 39891. S. No. 57–606 M.)

QUANTITY: 25 lbs. at Miami, Fla.

RESULTS OF INVESTIGATION: The article had been shipped, in unlabeled bundles contained in a clothes-type trunk, into Florida by an unknown carrier on an unknown date.

LIBELED: 3–7–57, S. Dist. Fla.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, as an aphrodisiac; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 5–9–57. Default—destruction.

5224. Apiarian Royal Jelly. (F. D. C. No. 39679. S. No. 24–981 M.)

QUANTITY: 12 12½-oz. jars at Seattle, Wash.

SHIPPED: 10–3–56, from Boise, Idaho, by Powers-Cosho Bee Culture Laboratories, Inc.

LABEL IN PART: "Apiarian Royal Jelly Rich in Vitamins and Minerals Contains 1600 mg. Queen Bee Royal Jelly in ½ pint of honey in the Pure Natural State."

ACCOMPANYING LABELING: Streamer reading "AT LAST APIARIAN ROYAL JELLY Produced by Powers Cosho Bee Culture Laboratories Inc. Is On The Market You Have Read About It In—Look, Harper's, Vogue, N. Y. Times, Coronet, Am. Bee Journal Contains most vitamins; especially high in B Complex and Pantothenic Acid (associated with prolongation of life)" and reprint entitled "Royal Jelly: a Review" by R. B. Willson, from the American Bee Journal, Hamilton, Ill.

LIBELED: 11–14–56, W. Dist. Wash.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was capable of giving one a feeling of youth and well-being; that it was effective to regenerate debilitated organs, cure nervous and vascular troubles, hemorrhoids, Parkinson's disease, speed up appetite, make prodigious our memories, make wrinkles disappear, and reactivate glands in glandular and nervous disorders, including aging; and that it was effective in treating cerebral neuritis, diabetes, asthma, failing eyesight, and sterility in women and impotency in men; and 505 (a)—the article was a new drug which may not be lawfully introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 4–15–57. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5225. Chlortetracycline capsules. (F. D. C. No. 39800. S. No. 14–486 M.)

QUANTITY: 5 unlabeled jars, 2,250 capsules total, at St. Louis, Mo.

SHIPPED: 11–9–56, from Louisville, Ky., by W. P. Medlock.

LIBELED: 12–3–56, E. Dist. Mo.

CHARGE: 502 (1)—the article, when shipped, was a drug *chlortetracycline*, requiring certification, and there was no certificate in effect for this lot of the drug.

DISPOSITION: 1–8–57. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

5226. Gray, white, and pink tablets containing amphetamine sulfate, thyroid, aloin, and phenobarbital. (F. D. C. No. 39836. S. Nos. 24–971/9 M, 33–532 M.)

INFORMATION FILED: 4–12–57, W. Dist. Okla., against S. Kloster Powell, Lawton, Okla.

SHIPPED: *Gray, white, and pink tablets containing amphetamine sulfate, thyroid, aloin, and phenobarbital,* between 6–13–56 and 8–18–56, from Oklahoma to Missouri and Washington.

CHARGE: 502 (b) (1) and (2)—the tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the tablets failed to bear a label containing the common or usual name of each active ingredient; and 502 (f) (1) and (2)—the labeling of the tablets failed to bear adequate directions for use and adequate warnings against use; and 503 (b) (4)—the tablets were drugs subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Nolo contendere.

DISPOSITION: 4–24–57. Defendant fined $500 and placed on probation for 5 years.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5227. Cathartic compound pills. (F. D. C. No. 39690. S. No. 37–307 M.)

QUANTITY: 86 cases, each containing 50 1,000-pill btls., at Brooklyn, N. Y.

SHIPPED: 1–5–55, from Edgewater, N. J.

LIBELED: 11–16–56, E. Dist. N. Y.

CHARGE: 502 (a)—the label of the article, while held for sale, bore the statement, "Caution: To be used only by or on the prescription of a physician," which was false and misleading since the statement represented that the article was restricted to prescription sale, when such was not the case; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement; and 502 (f) (2)—the article was essentially a laxative, and its labeling failed to warn that the article should not be taken when severe abdominal pains or other symptoms of appendicitis are present.

DISPOSITION: 6–18–57. Consent—claimed by Chemical Commodities, Inc., Olathe, Kans., and relabeled.

5228. Epsom salt. (F. D. C. No. 39850. S. No. 50–335 M.)

QUANTITY: 59 cases, 24 1-lb. boxes each, 40 cases, 24 ½-lb. boxes each, and 21 1-lb. boxes, at Boston, Mass., in possession of D & L Slade Co.

SHIPPED: 9–28–56, from Midland, Mich.

LABEL IN PART: (Box) "Slade's U. S. P. Epsom Salts."

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*See also No. 5221.

*See also Nos. 5221–5223, 5226.

RESULTS OF INVESTIGATION: The article was shipped in bulk, and after its receipt by D & L Slade Co., it was repacked into the containers described above.

LIBELED: 1–25–57, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use since no indications for use or dosage directions were given; and 502 (f) (2)—the article was essentially a laxative, and its labeling failed to warn that frequent or continued use may result in dependence on laxatives to move the bowels; and the labeling failed also to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present.

DISPOSITION: 2–19–57. Consent—claimed by D & L Slade Co. and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5229. Digitalis tablets. (F. D. C. No. 39683. S. No. 47–311 M.)

QUANTITY: 11 1,000-tablet btls. at Reading, Pa.

SHIPPED: 8–2–56, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

LABEL IN PART: (Btl.) "Enteric coated green 1,000 tablets Digitalis U. S. P. * * * 1½ grains."

RESULTS OF INVESTIGATION: The article was shipped in a bulk container labeled, in part, "Digitalis 1½ gr. Tablets Each Tablet contains Digitalis . . . 1½ gr.," and was repackaged and relabeled as above by the consignee.

Analysis showed that the digitalis potency of the article fell below its professed potency of 1½ grains of U. S. P. digitalis per tablet.

LIBELED: 11–9–56, E. Dist. Pa.

CHARGE: 501 (b)—the article purported to be and was represented as "Digitalis Tablets," a drug the name of which is recognized in the United States Pharmacopeia; and, when shipped and while held for sale, its strength differed from the standard set forth in such compendium; and 502 (a)—the label statement "Digitalis * * * 1½ grains" was false and misleading.

DISPOSITION: 2–7–57. Default—destruction.

5230. Nasal spray. (F. D. C. No. 39486. S. No. 52–694 M.)

QUANTITY: 828 btls. at Newark, N. J.

SHIPPED: 8–16–56, from Brooklyn, N. Y., by Success Chemical Co., Inc.

LABEL IN PART: (Btl.) "20 cc R/W Tyro-Hist Nasal Spray."

LIBELED: 9–25–56, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 0.02 percent of tyrothricin; and 502 (a)—the label statement "Contains in Aqueous Isotonic Solution: Tyrothricin . . . 0.02%" was false and misleading as applied to the article, which contained less than 0.02 percent of tyrothricin.

DISPOSITION: 11–14–56. Default—destruction.

5231. Halazone tablets. (F. D. C. No. 39708. S. Nos. 28–250 M, 28–298 M.)

QUANTITY: 400 cases, each containing 3 ctns. of 100 btls. each, at Oakland, Calif.

SHIPPED: On an unknown date, from Chicago, Ill.

LABEL IN PART: (Btl.) "100 Water Purification Tablets FOR PURIFYING DRINKING WATER IN CANTEENS HALAZONE N. N. R. * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

LIBELED: 11–30–56, N. Dist. Calif.

CHARGE: 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium; and its strength, while held for sale, differed from the standard set forth in such compendium.

DISPOSITION: 12–11–56. Default—destruction.

5232. Halazone tablets. (F. D. C. No. 39672. S. No. 37–306 M.)

QUANTITY: 188 cases, 300 btls. each, at Brooklyn, N. Y.

SHIPPED: 8–23–55, from Topeka, Kans.

LABEL IN PART: (Btl.) "Tablets Water Purification Individual (Halazone) 100 Tablets * * * Each tablet contains: P-Sulfonedichloramido Benzoic Acid (1/16 Grain) Sodium Carbonate Sodium Chloride Boric Acid" or "100 Water Purification Tablets For Purifying Drinking Water in Canteens * * * Halazone N. N. R. (P-sulfonedichloramido-benzoic acid) Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium borate and chloride."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 44 percent to 91 percent of the declared amount of halazone. The National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 11–9–56, E. Dist. N. Y.

CHARGE: 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength, while held for sale, differed from the standard set forth in such compendium.

DISPOSITION: 1–11–57. Default—destruction.

5233. Plastic adhesive strips. (F. D. C. No. 39671. S. No. 44–918 M.)

QUANTITY: 60 12-pkg. ctns. at Washington, D. C.

SHIPPED: 9–4–56, from New Rochelle, N. Y., by C. I. Lee & Co., Inc.

LABEL IN PART: (Pkg.) "10¾ x 3 New Plastic Adhesive Strips Washable Waterproof Individually Wrapped Sterilized."

RESULTS OF INVESTIGATION: Examination showed that the article was not sterile but was contaminated with viable micro-organisms.

LIBELED: 11–5–56, Dist. Columbia.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, "Adhesive Absorbent Bandage," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its quality and purity fell below the standard set forth in such compendium.

DISPOSITION: 12–5–56. Default—destruction.

5234. Clinical thermometers. (F. D. C. No. 39450. S. Nos. 48–862/3 M.)

QUANTITY: 28 doz. *oral thermometers* and 19 doz. *rectal thermometers* at Milwaukee, Wis.

SHIPPED: Between 3–24–56 and 7–3–56, from New York, N. Y., by the Philbern Thermometer Co., Inc.

LABEL IN PART: (Ctn.) "One Fever Thermometer * * * Philbern * * * Oral (Or Rectal)."

ACCOMPANYING LABELING: (Leaflet) "Certificate of Examination * * * The Government Bureau recognizes as reliable all thermometers having a correction of 2/10 of a degree at any test point * * * This clinical thermometer has been tested by a Standard Thermometer, approved by the Bureau of Standards, Washington, D. C., at the following degrees and found to stand at: 98°–0, 100°–0, 104°–0, 106°–0. If reading is plus then subtract from reading, if minus, add to reading."

RESULTS OF INVESTIGATION: Examination of 24 *oral thermometers* and 24 *rectal thermometers* showed that 6 oral thermometers and 7 rectal thermometers failed to meet the labeled standard of accuracy.

LIBELED: 8–29–56, E. Dist. Wis.

CHARGE: 501 (c)—the quality of the thermometers, when shipped, fell below that which they purported and were represented to possess since their actual temperature readings did not comply with the standard of accuracy claimed for them.

DISPOSITION: 10–11–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5235. Mino tablets. (F. D. C. No. 39642. S. Nos. 39–921/4 M.)

QUANTITY: 1 30,000-tablet drum, 3 40,000-tablet drums, 3 60,000-tablet drums, 405 100-tablet btls., 108 250-tablet btls., and 25 500-tablet btls. at Detroit, Mich., in possession of Wolverine Laboratories, Inc.

SHIPPED: Between 4–16–56 and 4–25–56, from St. Louis, Mo.

LABEL IN PART: (Drum) "W1–2 S. C. Brown Mino Revised Tablets"; (btl.) "Mino Tablets * * * New Improved Formula * * * Each Tablet Contains Thiamine Hcl .50 mg., Riboflavin 1.00 mg., Niacin .30 mg., Pyridoxine Hcl .01 Mg., Calcium Pantothenate .20 mg., Vitamin D 1000 U. S. P. Units, Tryptophane .55 mg., Cystine .70 mg., Histidine 1.50 mg., Methionine 2.00 mg., Isoleucine 2.50 mg., Arginine 3.00 mg., Phenylalanine 3.00 mg., Tyrosine 3.00 mg., Threonine 3.00 mg., Valine 3.50 mg., Lysine 4.00 mg., Leucine 9.00 mg., Pyrilamine Maleate 3.00 mg., Salicylamide 1.50 gr."

ACCOMPANYING LABELING: Leaflets entitled "Sinus Sufferers!," stickers entitled "Sinus!," and streamers entitled "Sinus! Try New Mino Tablets."

RESULTS OF INVESTIGATION: The article had been shipped in bulk. Upon receipt at Detroit, some had been repackaged into bottles and relabeled by the consignee. The bottle labels and the accompanying labeling had been printed locally for the consignee.

LIBELED: 10–22–56, E. Dist. Mich.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for overcoming sinus conditions, throbbing,

*See also Nos. 5221, 5224, 5227, 5229, 5230.

blinding migraine headaches, excruciating facial pains, nausea, and congested sinuses and sinus passages.

DISPOSITION: 12–3–56. Consent—claimed by Wolverine Laboratories, Inc., and relabeled.

5236. Late-Tabs and Fem-Tabs. (F. D. C. No. 39749. S. Nos. 43–565/6 M.)

QUANTITY: 5⅙ doz. btls., 18 tablets each, of *Late-Tabs*, and 5½ doz. btls., 18 tablets each, of *Fem-Tabs*, at St. Louis, Mo.

SHIPPED: 10–2–56, from Chicago, Ill., by Nature Brand Products.

LABEL IN PART: (Btl.) "Late-Tabs [or "Fem-Tabs"] * * * Each Tablet Contains: Culver's Root . . . 1 mg. Blood Root . . . 1 mg. Ladies' Mantle . . . 1 mg. Squaw Vine . . . 1 mg. Cramp Bark . . . 1 mg. Sheperd's Purse . . . 1 mg. Black Cohosh . . . 1 mg. Wind Flower . . . 1 mg."

ACCOMPANYING LABELING: Sheets entitled "Triple Your Money No Rx Required! * * * Late-Tabs * * * Fem-Tabs."

LIBELED: 1–11–57, E. Dist. Mo.

CHARGE: 502 (a)—the labeling of the articles, when shipped, namely, the names, "Fem-Tabs" and "Late-Tabs," the bottle labels, and the accompanying labeling, contained false and misleading representations that the articles were an adequate and effective treatment for irregular or delayed menses due to functional female disorders.

DISPOSITION: 2–11–57. Default—destruction.

5237. Medicinal tea (ground plant material). (F. D. C. No. 39010. S. No. 38–867 M.)

QUANTITY: 2 drums containing a total of 80 kilos of *ground plant material* in bulk and 12 3-oz. pkgs. of *ground plant material* at Hollywood, Fla., in possession of Goodwill's Pharmacy.

SHIPPED: 4–24–55 and 1–19–56, from Mennheim, Holland.

LABEL IN PART: (Pkg.) "Goodwill's Old German Formula D Tea A Popular Herbal Compound Non-Laxative * * * Aromatic Herbal Compound Ingredients: Foreign Lovage Root, Rest Harrow Root, Licorice Root, Speedwell Herb, Juniper Berries, Parsley and Anise Seeds. Packaged and Distributed by Goodwill Drug Company Hollywood, Florida" and "Goodwill's Old German Formula D Tea Nature's Diuretic Stimulant for the Kidneys * * * A compound of Imported Medicinal Herbs * * * Active Ingredients: Foreign Lovage Root, Rest Harrow Root, Licorice Root, Pansy Leaves and Flowers, Juniper Berries, Parsley and Anise Seeds. Goodwill Drug Company Hollywood, Florida."

ACCOMPANYING LABELING: Leaflet entitled "Goodwill's Old German Formula Diuretic Tea," a sign headed "Goodwill's Old German Formula D Tea," and streamers headed "D Tea Health From Herbs Tonic For Kidneys The Old German Formula Imported * * * Sold Here."

RESULTS OF INVESTIGATION: After receipt of the bulk *ground plant material*, Goodwill's Pharmacy repackaged a quantity of this material into 3-oz. packages labeled as described above. The pharmacy also had in its possession 4,000 empty packages bearing the same label as on the packages described above and various quantities of the above-mentioned accompanying labeling, which had been printed locally for Goodwill's Pharmacy.

LIBELED: 3–26–56, S. Dist. Fla.

CHARGE: 502 (a)—the package labels and the accompanying labeling of the article, while held for sale, contained false and misleading representations that the article was a tonic for the kidneys; that its use would make one feel good again and would keep old age away; that the article was a tonic for the stomach and an aid to digestion; that it would relieve kidney and bladder disorders; and that it would prevent and treat backache, arthritis, rheumatism, swollen ankles, and skin eruptions.

DISPOSITION: 5–28–56. Consent—claimed by Goodwill Drug Co. and relabeled.

5238. Primeval flowers honey. (F. D. C. No. 39748. S. No. 48–516 M.)

QUANTITY: 31 1-lb. jars, 18 2-lb. jars, and 16 3-lb. jars at Chicago, Ill.

SHIPPED: 11–13–56, from Smithtown, N. Y., by Organic Honey Farms, Inc.

LABEL IN PART: (Jar) "Genuine 100% Organic Primeval Flowers Honey * * * Exclusively gathered and packed by Organic Honey Farms, Inc. Jericho Turnpike Smithtown, New York."

LIBELED: 1–8–57, N. Dist. Ill.

CHARGE: 502(a)—the label of the article, when shipped, contained false and misleading representations that other brands of honey are not free of insecticides, arsonate of lead, and other impurities; that the article contained more vitamins, enzymes, and minerals than other honeys; that its flavor was superior to other honeys; and that the article strengthened the heart, liver, and pancreas, and all vital organs of the human system; and that a spoonful a day would keep the doctor away.

DISPOSITION: 2–13–57. Default—destruction.

5239. Holder's electronic condensator device. (F. D. C. No. 39495. S. No. 34–896 M.)

QUANTITY: 1 *Holder's Electronic Condensator device*, together with various accessories to be used with the device, at Covington, Ky.

SHIPPED: About April 1956, from Detroit, Mich., by Colo Products, Inc.

LABEL IN PART: (Device) "Holder's Electronic-Oscillating 'Condensator' Generating Fluid Electrically All Rights Protected Primordial Off On Ozone Off On Powder Med. High Compensator Control General Body Treatment Bi Polar Pact Only Eye-Ear-Nose-Throat Treatment Colo Products, Inc., Detroit, Mich. * * * Windsor, Can."

ACCOMPANYING LABELING: Booklet entitled "Holder's Electronic High-Frequency Condensator Operating Instructions."

RESULTS OF INVESTIGATION: This device was an electronic, high-voltage oscillator and a group of glass electrode applicators. The electrodes were gas-filled and produced a glow discharge during application. The radio frequencies emanating were of such low power and low frequency as to have negligible absorption in the body.

LIBELED: 10–2–56, E. Dist. Ky.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the device was effective for locating trouble areas and toxic conditions and for determining the seriousness of the condition; for treating all body ailments, including ailments of the eyes, ears, throat, tonsils, teeth, face, heart, lungs, liver, gallblader, kidneys, pan-

creas, spleen, stomach, bowels, anus, rectum, breast, ovaries, uterus, vagina, cervix, brain, and frontal sinus; and for treating abscess, anemia, arthritis, rheumatism, paralysis, hay fever, hemorrhoids, varicose veins, leg ulcers, multiple sclerosis, mucous colitis, malnutrition, pain, influenza, indigestion, head noises, and allergic conditions due to a large variety of products.

DISPOSITION: 12–3–56. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

5240. Lasus Piperol. (F. D. C. No. 39865. S. Nos. 48–447/9 M.)

QUANTITY: 3 1-gal. btls., 18 1-qt. btls. and 19 1-pt. btls. at Simpson, Ind.

SHIPPED: 6–27–56, from Toledo, Ohio, by Lasus Bros. Chemical Co.

LABEL IN PART: (Btl.) "Lasus Piperol Liquid Wormer for Swine and Poultry Removing and Control of Nodular and Round Worms from Swine and Large Round Worms * * * and Cecal Worms * * * from Poultry. Active Ingredient: Each 100 cc contains 17.08 grams of Piperazine Base Hexahydrate * * * DIRECTIONS FOR USE *Chickens:* Quantity for 100 birds: 4–8 weeks old—Mix 1 ounce of Piperol to 1 gallon drinking water. 8–12 weeks old—Mix 2 ounces of Piperol to 2 gallons drinking water. Over 12 weeks old—Mix 2 ounces of Piperol with 3 gallons drinking water. *Turkeys:* Quantity for 100 birds: Under 12 weeks old—Mix 2 ounces of Piperol to 8 gallons of drinking water. Over 12 weeks old—Mix 2 ounces of Piperol to 10 gallons of drinking water. Over 20 lbs. of weight—Mix 3 ounces of Piperol with 15 gallons of drinking water. *Swine:* 1 ounce Piperol mixed with 1 gallon drinking water for each 100 lbs. of live weight of swine as only source of drinking water in pen. Do not take away remedy until consumed. Worm infested swine should be treated in the morning."

RESULTS OF INVESTIGATION: The article, when administered in the manner directed by the above label, did not provide a sufficient dosage of piperazine to remove and control nodular worm and round worm infestation in swine; and piperazine is not effective for treating cecal worm infestation in poultry.

LIBELED: 2–7–57, N. Dist. Ind.

CHARGE: 502 (a)—the label of the article, when shipped, contained false and misleading representations that, when administered in the manner directed, the article was an adequate and effective treatment for nodular worm and round worm infestation in swine and cecal worm infestation in poultry.

DISPOSITION: 4–4–57. Default—destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE 1954

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5241–5280

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *September 16, 1958.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

5241. (F. D. C. No. 38147. S. Nos. 4–938/40 M, 5–023/4 M, 5–085 M.)

INDICTMENT RETURNED: 11–16–55, N. Dist. Ind., against **Max Capestany, Jr., t/a Central Pharmacy, Gary, Ind.**

CHARGE: Between 1–10–55 and 3–17–55, *Pentids tablets* (penicillin G potassium) and *Citramine Racemic tablets* (amphetamine sulfate) were each dispensed twice, and *Vaginola capsules* (containing ergot and apiol) and *Savatan capsules* (containing apiol) were each dispensed once, without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court on 2–20–57, and was terminated with the return by the jury of a verdict of guilty. On 3–22–57, the court imposed a fine of $500 on each count, a total fine of $3,000, plus costs, and a sentence of 3 years in jail on count 1. The court suspended the jail sentence, withheld the imposition of sentence on the remaining 5 counts of the indictment, and placed the defendant on probation for 5 years.

5242. **Supplement to notice of judgment on drugs and devices, No. 4965. Violation of probation.** (F. D. C. No. 38575. S. Nos. 40–858 M, 56–606 M, 56–610 M, 56–613 M.)

On 2–8–56, upon a plea of guilty to the charge of dispensing *Dexedrine Sulfate tablets* 3 times without a prescription, the defendant, **John L. Schulte, t/a Schulte Drug Store, Sioux City, Iowa,** was given a sentence of 6 months in prison, which was suspended, and placed on probation for 30 months.

On 2–1–57, the defendant was brought before the court on a charge of violating his probation by dispensing *Dexedrine Sulfate tablets* 3 times upon requests for prescription refills without authorization by the prescriber and *Dexedrine Spansule capsules* once without a prescription. The defendant pleaded not guilty; and after a hearing in the matter, the court, on 2–1–57, continued the defendant's probation for an additional period of 30 months on condition that the defendant completely disassociate himself from the drugstore business owned and operated by him, and that the defendant shall not dispense any drugs or engage in any employment or activity with respect to the dispensing of drugs.

5243. **Supplement to notice of judgment on drugs and devices, No. 4973. Violation of probation.** (F. D. C. No. 38523. S. Nos. 34–190/2 M, 34–195/6 M.)

On 3–21–56, upon a plea of nolo contendere to the charge of dispensing *Seconal Sodium capsules* 5 times upon requests for prescription refills without authorization by the prescriber, the defendant, **Stanley M. Meyers, t/a Meyers Professional Pharmacy, Topeka, Kans.,** was fined $500 and placed on probation for 2 years.

On 3–20–57, the defendant was brought before the court on a charge of violating his probation by dispensing, between 10–5–56 and 10–23–56, *Dexedrine Sulfate tablets* 3 times and *Nembutal Sodium capsules* twice upon requests for prescription refills without authorization by the prescriber. Arrangements were made for further hearing in the matter; and, pursuant thereto, the defendant appeared before the court on 4–22–57. At the conclusion of the hearing on 4–22–57, the court continued the defendant's probation and ordered that the defendant make monthly reports to the probation officer.

5244. (F. D. C. No. 39401. S. Nos. 39–974/5 M, 56–003 M.)

INFORMATION FILED: 4–2–57, N. Dist. Ill., against **Schlachet Drug Co., Inc., Chicago, Ill., and Seymour Eisen (president and pharmacist).**

CHARGE: Between 3–2–56 and 5–24–56, *Seconal Sodium capsules* were dispensed once and *Butazolidin tablets* were dispensed twice, upon request for a prescription refill without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 5–6–57. Corporation—$150 fine, plus costs; Eisen—$300 fine.

5245. F. D. C. No. 38525. S. Nos. 10–851 M, 10–854 M, 11–285/7 M, 11–296 M, 11–298 M.)

INFORMATION FILED: 5–18–56, E. Dist. La., against **Smith's Drug Store (a partnership), New Orleans, La., and Isidore Smith (partner) and Clement E. Cline (pharmacist).**

CHARGE: Between 7–6–55 and 7–24–55, *paraldehyde* (counts 1, 2, 4, and 7) was dispensed 4 times, *Tri-Sulfanyl tablets* (counts 3 and 5) were dispensed twice, and *pentobarbital sodium capsules* (count 6) were dispensed once, upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty—by partnership to all 7 counts of information; by Isidore Smith to count 7; and by Clement E. Cline to counts 1, 4, and 6.

DISPOSITION: 9–19–56. $100 fine against each defendant.

5246. (F. D. C. No. 39399. S. Nos. 56–261 M, 56–264 M, 56–266/9 M.)

INFORMATION FILED: 3–19–57, N. Dist. Ill., against **Ben Vold, Inc., Chicago, Ill., and Seymour G. DeKoven (president and assistant pharmacist).**

CHARGE: Between 5–7–56 and 6–11–56, *dextro-amphetamine sulfate tablets* and *pentobarbital sodium capsules* were each dispensed twice and *sulfadiazine tablets* and *Metandren Linguets* were each dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 4–8–57. $600 fine against each defendant, plus costs.

5247. (F. D. C. No. 39962. S. Nos. 47–038 M, 47–040 M, 47–065/6 M.)

INFORMATION FILED: 2–26–57, Dist. N. J., against **Arnold F. Bowker, t/a Bowker's Pharmacy, Milford, N. J., and John V. Dougherty (pharmacist).**

CHARGE: Between 9–29–56 and 10–30–56, *capsules containing a mixture of ergot, apiol, and oil of savin* (counts 1 and 4), and *Tuinal capsules* (counts 2 and 3), were each dispensed twice without a prescription.

PLEA: Guilty—by Bowker to count 1 and by Dougherty to counts 2, 3, and 4.

DISPOSITION: 4–1–57, Dougherty—fined $150 and placed on probation for 1 year; 4–15–57, Bowker—fined $250 and placed on probation for 6 months.

5248. (F. D. C. No. 39966. S. Nos. 52–212/3 M, 52–215 M, 52–326 M, 52–336 M.)

INFORMATION FILED: 3–21–57, E. Dist. N. Y., against **Norman Janks, t/a Franklin Pharmacy, Garden City, N. Y., and Maynard Horin (pharmacist).**

CHARGE: Between 4–20–56 and 5–23–56, *AM Plus capsules* were dispensed once without a prescription and *Metandren tablets* were dispensed once and *Seconal Sodium capsules* were dispensed 3 times upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by Janks to dispensing the *AM Plus capsules* and the *Metandren tablets* and to dispensing the *Seconal Sodium capsules* twice, and by Horin to dispensing the *Metandren tablets* and to dispensing the *Seconal Sodium capsules* once.

DISPOSITION: 5–2–57. Janks—$800 fine; Horin—$200 fine.

5249. (F. D. C. No. 39839. S. Nos. 34–185/6 M.)

INFORMATION FILED: 5–14–57, Dist. Kans., against **Orval T. Locke, t/a Locke's Drug Store, Concordia, Kans.**

CHARGE: Between 9–4–56 and 9–12–56, *Dexedrine Sulfate tablets* and *Desoxyn Hydrochloride tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–14–57. $200 fine, plus costs.

5250. (F. D. C. No. 39961. S. Nos. 13–597/600 M, 47–021/2 M.)

INFORMATION FILED: 2–21–57, Dist. N. J., against **Gerald B. Rednor, t/a Dupont Pharmacy, Trenton, N. J.**

CHARGE: Between 6–6–56 and 6–21–56, *tetracycline capsules* were dispensed once, *capsules containing apiol and ergot* were dispensed twice, and *dextroamphetamine sulfate tablets* were dispensed 3 times, without a prescription.

PLEA: Guilty.

DISPOSITION: 3–18–57. $250 fine and defendant placed on probation for 1 year.

5251. (F. D. C. No. 39826. S. Nos. 45–519/21 M.)

INFORMATION FILED: 2–15–57, Dist. Colo., against **Chester H. Erickson (manager of Tremont Drug), Denver, Colo.**

CHARGE: Between 3–24–56 and 3–28–56, *Desoxyn Hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–26–57. $750 fine; jail sentence suspended and defendant placed on probation for 3 years.

5252. (F. D. C. No. 40024. S. Nos. 30–855 M, 35–277 M, 35–280 M, 55–022 M.)

INFORMATION FILED: 5–24–57, W. Dist. Ky., against **Jewell V. Floyd, t/a Floyd's Drug Store, Elizabethtown, Ky.**

CHARGE: Between 7–31–56 and 10–25–56, *penicillin G procaine capsules* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–14–57. $300 fine.

5253. (F. D. C. No. 38623. S. Nos. 1–614 M, 1–643 M, 1–653 M, 1–656/7 M.)

INFORMATION FILED: 8–9–56, S. Dist. Fla., against **Leonard Berger, t/a Park Drug Co., Okeechobee, Fla., and Joseph H. Pearce (pharmacist).**

CHARGE: Between 5–19–55 and 8–22–55, *Selsun Suspension* and *cortisone acetate tablets* were each dispensed once without a prescription and *Seconal Sodium capsules* were dispensed 3 times upon request for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 9–7–56. Pearce—$100 fine. Berger—$1,000 fine; jail sentence withheld and probation for 2 years, conditioned that he not dispense drugs during that period.

5254. (F. D. C. No. 39407. S. Nos. 52–232/5 M, 52–251 M.)

INFORMATION FILED: 3–20–57, E. Dist. N. Y., against **Lawrence Drug Co. (a partnership), Lawrence, N. Y., and Joseph G. Rothkopf (partner and pharmacist), Harry Rothkopf (partner and clerk), and Alvin Eichler (pharmacist).**

CHARGE: Between 4–20–56 and 5–24–56, *Seconal Sodium capsules* were dispensed 4 times (counts 1 through 4) upon request for a prescription refill without authorization by the prescriber and *AM Plus capsules* were dispensed once (count 5) without a prescription.

PLEA: Guilty—by partnership to all 5 counts, by J. G. Rothkopf to counts 1 and 4, by H. Rothkopf to counts 2 and 5, and by Eichler to count 3.

DISPOSITION: 4–25–57, partnership—$1,250 fine; J. G. Rothkopf—$1,500 fine. 5–2–57, H. Rothkopf—$1,000 fine; Eichler—$500 fine.

5255. (F. D. C. No. 39397. S. Nos. 55–981 M, 55–984/5 M, 55–987 M, 55–996/7 M.)

INFORMATION FILED: 2–28–57, N. Dist. Ill., against **Buena Drug Store (a partnership), Chicago, Ill., and Emmanuel H. Wasserman (apprentice pharmacist).**

CHARGE: Between 4–26–56 and 5–3–56, *Gantrisin tablets* were dispensed 3 times and *apiol-ergot compound capsules* and *Ergotrate Maleate tablets* were each dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 3–19–57. Partnership—$100 fine; Wasserman—$350 fine.

5256. (F. D. C. No. 38597. S. Nos. 14–740 M, 14–747 M, 14–754/5 M, 30–157 M.)

INFORMATION FILED: 5–31–56, S. Dist. Ill., against **Howard Drugs, Inc., Collinsville, Ill., and Sam Bierman (president).**

CHARGE: Between 6–29–55 and 7–22–55, *triple sulfa tablets* and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription and *secobarbital sodium capsules, dextro-amphetamine sulfate tablets*, and *phenobarbital tablets* were each dispensed once upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6–14–56. $500 fine against each defendant, with payment of fine against individual to constitute full satisfaction of corporation's fine.

5257. (F. D. C. No. 39331. S. Nos. 33–033 M, 33–039/42 M.)

INFORMATION FILED: 7–30–56, Dist. Utah, against **John E. Booth (partner in World Drug Co.), Spanish Fork, Utah.**

CHARGE: Between 12–12–55 and 1–4–56, *Edrisal tablets, secobarbital sodium tablets*, and *pentobarbital sodium capsules* were each dispensed once without a prescription and *Amphedex tablets* and *Premarin tablets* were each dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 11–15–56. $2,500 fine.

5258. (F. D. C. No. 39349. S. Nos. 27–964 M, 27–970 M, 28–083 M, 28–088 M, 39–208 M.)

INFORMATION FILED: 2–13–57, N. Dist. Ga., against **V. M. Williams, t/a Williams Pharmacy, Atlanta, Ga., and George N. Snelling (pharmacist).**

CHARGE: Between 2–23–56 and 3–5–56, *penicillin tablets* (count 1), *Dexedrine Sulfate tablets* (count 2), and *dextro-amphetamine sulfate tablets* (count 5) were each dispensed once, and *Bicillin oral suspension* (counts 3 and 4) was dispensed twice, without a prescription.

PLEA: Nolo contendere by Williams to count 4 and by Snelling to remaining counts of information.

DISPOSITION: 3–11–57 with respect to Snelling and 9–9–57 with respect to Williams; each defendant placed on probation for 2 years.

5259. (F. D. C. No. 40023. S. Nos. 55–107 M, 55–115/6 M, 55–125 M, 55–144 M.)

INFORMATION FILED: 5–21–57, S. Dist. Ohio, against **Ross C. Spinning and Leonard Zakem (pharmacists for Sloan Drug Co.), Fairborn, Ohio.**

CHARGE: Between 4–30–56 and 9–10–56, *penicillin G potassium tablets* (count 1), *buffered penicillin G potassium tablets* (count 2), and *Ethchlorvynol capsules* (count 3) were each dispensed once, and *Dexedrine Spansule capsules* (counts 4 and 5) were dispensed twice, without a prescription.

PLEA: Guilty.

DISPOSITION: 5–31–57. Spinning—$250 fine on each of counts 1 and 5, a total of $500; Zakem—$200 fine on each of counts 2 and 4 and $100 on count 3, a total of $500.

5260. (F. D. C. No. 40019. S. Nos. 39–970/2 M, 56–222 M.)

INFORMATION FILED: 6–3–57, N. Dist. Ill., against **Goldsmith Drug Co., Inc., Chicago, Ill., and Paul Goldsmith (vice president and secretary) and Frank Marinelli (pharmacist).**

CHARGE: Between 6–29–56 and 10–25–56, *Ergoapiol with savin capsules, penicillin G potassium tablets, Ergotrate Maleate tablets,* and *apiol-ergot compound capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere by corporation and Goldsmith to all 4 counts of information and by Marinelli to counts involving dispensing of *Ergotrate Maleate tablets* and *apiol-ergot compound capsules.*

DISPOSITION: 6–24–57. Corporation fined $100, plus costs; Goldsmith, $400; and Marinelli, $100.

5261. (F. D. C. No. 40004. S. Nos. 38–383 M, 38–402/3 M, 38–408 M, 38–703 M, 38–705 M.)

INFORMATION FILED: 4–16–57, E. Dist. Ill., against **Robert Gaffner Co. (a corporation), Olney, Ill., and Robert L. Blackburn (president), Robert C. Edwards (pharmacist), and Charles A. Webster (pharmacist).**

CHARGE: Between 6–26–56 and 8–3–56, *sulfisoxazole tablets* (count 2) and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* (count 4) were each dispensed once, and *thyroid tablets* (counts 1 and 5) and *dextro-amphetamine sulfate tablets* (counts 3 and 6) were each dispensed twice, without a prescription.

PLEA: Guilty by corporation to all counts; by Blackburn to counts 5 and 6; by Edwards to counts 3 and 4; and by Webster to counts 1 and 2.

DISPOSITION: 4–30–57. Corporation—$500 fine, plus costs; Blackburn, Edwards, and Webster—each $250 fine, plus costs.

5262. (F. D. C. No. 40021. S. Nos. 34–253/6 M.)

INFORMATION FILED: 7–9–57, W. Dist. Okla., against **Ira L. Rowe, t/a Buck Rowe's Drug, Ponca City, Okla., and William H. Hester (employee).**

CHARGE: Between 8–23–56 and 10–29–56, *Achromycin tablets* were dispensed 4 times without a prescription.

PLEA: Nolo contendere by Rowe to each of 4 counts of information and by Hester to 3 counts.

DISPOSITION: 9–6–57. Rowe fined $40 and Hester $30.

5263. (F. D. C. No. 39994. S. Nos. 62–066 M, 62–075 M.)

INFORMATION FILED: 5–24–57, S. Dist. N. Y., against **White Plains Drug Co., Inc., White Plains, N. Y., and Henry A. Petruzzi (president of the corporation).**

CHARGE: On 9–26–56, *Metandren tablets* and *Gantrisin* tablets were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–18–57. Corporation fined $200 and individual $100.

5264. (F. D. C. No. 40005. S. Nos. 33–501/2 M, 33–504/5 M, 33–507/8 M.)

INFORMATION FILED: 9–13–57, W. Dist. Mo., against **Blaylock's Pharmacy (a partnership), Kansas City, Mo., and Fred O. Blaylock (partner).**

CHARGE: Between 6–13–56 and 7–7–56, *Metandren Linguets*, *Gantrisin tablets*, and *Somnos elixir* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1–3–58. Individual fined $1,200, plus costs; sentence suspended against partnership.

5265. (F. D. C. No. 40008. S. Nos. 52–448 M, 52–455 M, 52–457 M, 52–599 M.)

INFORMATION FILED: 7–2–57, S. Dist. N. Y., against **Jacob Bosser and Sheppard Greenberg (partners in the partnership of Bosser Pharmacy), Bronx, N. Y.**

CHARGE: Between 9–12–56 and 9–27–56, *Gantrisin tablets*, *Dexedrine Sulfate tablets*, *Metandren Linguets*, and *Seconal Sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty by Greenberg to act of dispensing *Gantrisin tablets* and by Bosser to other acts of dispensing charged.

DISPOSITION: 11–14–57. Bosser—$3,000 fine and imprisonment for 1 year; Greenberg—$1,000 fine and imprisonment for 6 months. Motions filed subsequently for reduction of sentences; motions denied on 11–25–57.

5266. (F. D. C. No. 37259. S. Nos. 82–032/3 L, 82–035 L. 82–037/41 L.)

INDICTMENT RETURNED: 6–9–56, Dist. Nebr., against **Willard H. Quigley, t/a Edward Drug Store, and Amiel F. Urban, (pharmacist).**

CHARGE: Between 7–2–54 and 9–26–54, a drug consisting of a number of *Gantrisin tablets* was dispensed 4 times upon request for a prescription refill without authorization by the prescriber, and a drug consisting of a number of *green, yellow, and pink tablets containing, among other ingredients, amphetamine hydrochloride, thyroid, atropine sulfate, aloin, and phenobarbital*, was dispensed once upon request for a prescription refill without authorization by the prescriber and 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 12–4–56. At the conclusion of the testimony, the court sustained the defendants' motion for a directed verdict and instructed the jury to return a verdict of not guilty as to each defendant, which was done on 12–11–56.

5267. (F. D. C. No. 39208. S. Nos. 33–822 M, 33–856/7 M.)

INDICTMENT RETURNED: 1–9–57, N. Dist. Okla., against **Roy T. Walker, t/a Walker Drug Store, Miami, Okla.**

CHARGE: Between 4–10–56 and 5–7–56, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 2–5–57. The trial was concluded on 2–8–57, with the return by the jury of a verdict of guilty. On 3–5–57, the court fined the defendant $1,000 and placed him on probation for 3 years.

5268. (F. D. C. No. 39358. S. Nos. 39–006 M, 39–010 M, 39–541 M.)

INFORMATION FILED: 12–26–56, M. Dist. N. C., against **Harry G. Julian, t/a Piedmont Truck Stop, and J. M. Ashley, (employee).**

CHARGE: Between 5–31–56 and 6–6–56, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 12–4–57. Julian fined $1,000 and Ashley fined $500. Each defendant placed on probation for 2 years.

5269. (F. D. C. No. 39338. S. No. 1–710 M.)

INFORMATION FILED: 2–13–57, N. Dist. Ga., against **Walter V. Kegley, t/a Hoke's Truck Stop, Marietta, Ga., and Donald Collins (employee).**

CHARGE: On 5–20–55, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–18–57. Each defendant placed on probation for 2 years.

5270. (F. D. C. No. 39372. S. Nos. 39–138 M, 39–140 M, 39–148 M, 39–307 M.)

INFORMATION FILED: 4–1–57, S. Dist. Fla., against **Kenny Alfred Turner, Oceanway, Fla.**

CHARGE: Between 5–9–56 and 5–31–56, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 12–6–57. Defendant sentenced to 9 months in prison.

5271. **Amphetamine sulfate tablets.** (F. D. C. No. 38527. S. Nos. 35–551/3 M.)

INFORMATION FILED: 9–26–57, N. Dist. Ill., against **Calvert Restaurant & Drugs (a partnership), Chicago, Ill., and Morris Korzen (partner).**

RESULTS OF INVESTIGATION: A quantity of amphetamine sulfate in bulk was shipped in interstate commerce to Chicago, Ill., and after its arrival, it was tableted and delivered to the defendants.

CHARGE: Between 9–19–55 and 10–24–55, the defendants caused the above-described *amphetamine sulfate tablets* to be dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–29–57. Each defendant fined $150, plus costs.

5272. (F. D. C. No. 38162. S. Nos. 1–713/4 M, 1–735/6 M, 1–758/9 M.)

INFORMATION FILED: 10–25–55, N. Dist. Ga., against **Homer F. Martin, t/a Nightingale Truck Stop, Griffin, Ga., and Robert Wadsworth (manager).**

CHARGE: Between 5–21–55 and 6–8–55, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty by Martin to all 6 counts of information and by Wadsworth to 4 counts of information.

DISPOSITION: 5–7–56. Martin fined $250, given jail sentence of 1 year and 1 day, which was suspended, and placed on probation for 2 years. Wadsworth placed on probation for 6 months.

5273. (F. D. C. No. 38532. S. No. 1–740 M.)

INFORMATION FILED: 10–25–55, N. Dist. Ga., against **James Clarence Osborne (partner in Twin Pines Drive Inn), near Dallas, Ga., and Myrtle Roberts (employee at the inn).**

CHARGE: On 5–31–55, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–14–56. Osborne fined $150 and Roberts placed on probation for 2 years.

5274. (F. D. C. No. 38529. S. Nos. 1–708/9 M, 1–731 M.)

INFORMATION FILED: 10–25–55, M. Dist. Ga., against **Frank Colley Ware (manager of Thornton's Cafe), on Highway U. S. 29, 3 miles from Royston, Ga.**

CHARGE: Between 5–18–55 and 5–27–55, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–4–56. Sentence of 6 months in prison.

5275. (F. D. C. No. 39362. S. Nos. 52–422/4 M, 52–426 M, 52–581 M, 52–583 M.)

INFORMATION FILED: 12–19–56, Dist. N. J., against **Station Pharmacy (a partnership), Newark, N. J., and Morris Goldstein (partner).**

CHARGE: Between 4–18–56 and 4–24–56, *Dexedrine Sulfate tablets* were dispensed 3 times and *Seconal Sodium capsules* were dispensed twice without a prescription, and *Dexedrine Sulfate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 1–25–57. Partnership fined $300; individual, $600.

5276. (F. D. C. No. 39379. S. Nos. 26–100 M, 40–802 M.)

INFORMATION FILED: 2–28–57, Dist. Minn., against **Lumber Exchange Drug, Inc., Minneapolis, Minn., and Clem F. Claseman (pharmacist).**

CHARGE: Between 2–15–56 and 2–23–56, *Dexedrine Spansule capsules* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–30–57. Corporation fined $100; individual, $300.

5277. (F. D. C. No. 39190. S. Nos. 34–822/4 M.)

INFORMATION FILED: 11–8–56, S. Dist. Ind., against **Basil F. McGhee, Switz City, Ind.**

CHARGE: Between 10–12–55 and 10–13–55, *desoxyephedrine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3–29–57. $300 fine, plus costs.

5278. (F. D. C. No. 38587. S. Nos. 476/7 M, 19–670 M, 19–672 M.)

INFORMATION FILED: 4–11–56, S. Dist. Ind., against **Harold F. Wurster, t/a Wurster Pharmacy, Indianapolis, Ind.**

CHARGE: Between 9–13–55 and 9–14–55, *dextro-amphetamine sulfate tablets* were dispensed twice and *secobarbital sodium capsules* were dispensed once without a prescription, and *dextro-amphetamine sulfate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 7–25–57. Jail sentence of 1 year suspended; defendant placed on probation for 2 years and required to pay court costs.

5279. (F. D. C. No. 39355. S. Nos. 1–633/4 M, 1–649 M, 1–661/2 M.)

INFORMATION FILED: 12–14–56, S. Dist. Fla., against **Glenn K. Stuart, t/a Park Pharmacy, Fort Lauderdale, Fla.**

CHARGE: Between 7–5–55 and 8–23–55, *Seconal Sodium Capsules* were dispensed 3 times and *cortisone acetate tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 6–24–57. $250 fine.

5280. (F. D. C. No. 38631. S. Nos. 973 M, 1–088 M, 27–822 M, 27–869 M, 27–886/7 M.)

INFORMATION FILED: 7–2–56, M. Dist. N. C., against **William Franklin Rhodes (pharmacist for Airheart's Drug Store), Concord, N. C.**

CHARGE: Between 6–14–55 and 10–25–55, *penicillin G potassium tablets* and *penicillin-bacitracin troches* were each dispensed once without a prescription, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 4 times upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10–15–56. Defendant fined $1,000 and placed on probation for 2 years.

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PRODUCTS

[1] (5241, 5266, 5267) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5241, 5266, 5267) Prosecution contested.
[2] (5242, 5243) Violation of probation.

67) Prosecution contested.

[1] (5241, 5266, 5267) Prosecution contested.
[2] (5242, 5243) Violation of probation.

[1] (5241, 5266, 5267) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1958

D. D. N. J., F. D. C. 5281–5300 Issued October 1958

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5281–5300

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, trial, or granting of a motion for summary judgment; or (2) criminal proceedings terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *October 1, 1958.*

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477790—58——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5281–5300

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy or decomposed substance; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

New drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5281. Pyradex. (F. D. C. No. 40108. S. No. 60–314 M.)

QUANTITY: 65 vials at Detroit, Mich.

SHIPPED: 1–24–57, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: (Vial) "10 cc Multiple Dose Vial * * * Pyradex with Dextro Amphetamine Hcl * * * Intramuscular only * * * Each cc contains a sterile aqueous solution of Pyranisamine Maleate . . . 25 mgm. * * * Indications: Hay fever, Nonseasonal allergic and Vasomotor Rhinitis, Asthma, Urticaria, Eczema and Dermatitis. Dosage: 1cc intramuscularly daily."

LIBELED: 3–26–57, E. Dist. Mich.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 5–13–57. Default—destruction.

5282. Pega Palo vine. (F. D. C. No. 40122. S. No. 70–971 M.)

QUANTITY: 470 cellophane pkgs. at Kimball, S. Dak.

SHIPPED: 2–18–57, from A–1 Import Co., Chicago, Ill., by Oliver Olson.

LABEL IN PART: "Pega Palo Vine Chicago, Illinois."

ACCOMPANYING LABELING: Reprints of an article entitled "Pega Palo The Vine That Makes You Virile," from the January 1957 issue of Confidential magazine.

RESULTS OF INVESTIGATION: Examination showed that each package of the article contained a piece of dried, woody, vine-like material.

LIBELED: 4–5–57, Dist. S. Dak.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the drug was intended; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since

an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 5–9–57. Consent—portion of article delivered to Food and Drug Administration and remainder destroyed.

5283. Pega Palo vine. (F. D. C. No. 40092. S. No. 72–887 M.)

QUANTITY: 33 cellophane pkgs. at Salt Lake City, Utah.

SHIPPED: On 1–31–57, D. H. Farrell and Al Cavey purchased the article from A–1 Import Co., Chicago, Ill., and personally transported it from Chicago to Salt Lake City.

ACCOMPANYING LABELING: Reprints of an article entitled "Pega Palo The Vine That Makes You Virile."

LIBELED: 3–20–57, Dist. Utah.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for its use as an aphrodisiac and as a sex rejuvenator, which were the purposes for which the article was intended; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–8–57. Default—the article and some of the reprints were delivered to the Food and Drug Administration, and the remainder of the reprints were destroyed.

5284. Pago (Pega) Palo vine. (F. D. C. No. 40096. S. No. 57–605 M.)

QUANTITY: 104 9-gram pkgs. at Miami Beach, Fla., in possession of Alfred J. Hardwick, d/b/a/ Bud Brownell.

SHIPPED: 12–21–56, from Dominican Republic, by Alfred J. Hardwick.

LABEL: (Pkg.) "Pago Palo Health Fountain of Youth Not For Sale To Persons Under 21 Years Of Age! For Steeping in Whiskey, Rum, Gin, Wine, Cognac, etc. Directions: Insert contents of pack into fifth of liquor. Allow to steep 3 days. For best results, wait one week. If more sweetness is desired, add raisins or caramel. Recommended Dosage: 3 ounces daily for three days. Thereafter 2 to 3 ounces weekly or at user's discretion. Note: Pago Palo in its vine form may be re-steeped repeatedly before its potency diminishes. This pack should constitute a one year's supply. Pago Palo Distributors * * * Hialeah, Fla."

RESULTS OF INVESTIGATION: The above packages were repacked from a 20-pound bulk shipment. Examination of the article showed it to consist of pieces of plant material resembling stem tissue. The pieces were 3 to 5 inches long and ¼- to ½-inch wide and appeared to be mostly flattened or longitudinally split stems. The surfaces of the whole stems appeared to be a thin brown bark, the interiors being hard and mildly woody with some pith areas. Splinters had no taste but a faintly musty odor.

LIBELED: 3–22–57, S. Dist. Fla.

CHARGE: 505 (a)—The article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate

directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 5–9–57. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR VETERINARY USE

5285. Dr. Clarno's Vita-Miacin for calves, cattle, and cows, and Dr. Clarno's Vita-Miacin for poultry. (F. D. C. No. 39273. S. Nos. 40–388/9 M.)

QUANTITY: 3 cases, 6 tins each, of *Dr. Clarno's Vita-Miacin for calves, cattle, and cows*, and 1 case, 6 tins each, of *Dr. Clarno's Vita-Miacin for poultry*, at Waterloo, Iowa.

SHIPPED: 4–17–56, from Rockford, Ill. This was a return shipment.

LABEL IN PART: (Tin) "Dr. Clarno's Vita-Miacin For Calves—Cattle—Cows 3 lbs. * * * Guaranteed Analysis Chlortetracycline (Aureomycin) Hydrochloride . . . . 4.00 Grams per lb." and "Dr. Clarno's Vita-Miacin For Poultry 3½ lbs. * * * Guaranteed Analysis Chlortetracycline (Aureomycin) Hydrochloride . . . 3.20 Grams per lb."

LIBELED: 6–9–56, N. Dist. Iowa.

CHARGE: 502 (1)—when shipped, the articles contained chlortetracycline and were not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 9–7–56. Consent—claimed by Dr. Clarno Products Co., Waterloo, Iowa, and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5286. Various drugs. (F. D. C. No. 38989. S. Nos. 38–108/12 M.)

QUANTITY: 550 4-oz. jars and 603 2-oz. jars of *Wonda Foot Balm*, 96 10-tablet boxes and 3 200-tablet btls. of *Wonda Mineral Foot and Body Bath*, 1,286 boxes of *Wonda Stone*, and 3,916 envelopes, each containing 1 tablet, of *Wonda Mineral Foot Bath*, at St. Louis, Mo., in possession of R. M. Ready.

SHIPPED: Between 1–10–56 and 1–19–56, from New York, N. Y., by Almo Products Corp.

LABEL IN PART: (Jar) "Nature's Medicated Wonda Foot Balm Contains Activated Lanolin Menthol–Eucalyptus Hexachlorophene G 11"; (box and btl.) "Wonda Mineral Foot & Body Bath Tablets * * * Contents: Aluminum Potassium-Sulphate Pine Oil Compound – Sodium Bicarbonate – Citric Acid and Eucalyptus Oil"; (box) "Nature's Wonda Stone Natural Volcanic Lava"; (envelope) "New 'Wonda' * * * Mineral Foot Bath * * * Contains: Aluminum Potassium Sulphate – Pine Oil Compound – Sodium Bicarbonate – Citric Acid and Eucalyptus Oil."

ACCOMPANYING LABELING: Circular entitled "Wonda Insurance Policy For Complete Foot Comfort."

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*See also Nos. 5282–5284.

RESULTS OF INVESTIGATION: After shipment, the articles were offered for sale at St. Louis, Mo., by R. M. Ready, a representative of the shipper. In promoting such sale, Mr. Ready orally represented that the articles were intended for use for the conditions and purposes set forth below.

LIBELED: 3–14–56, E. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the articles, while held for sale, failed to bear adequate directions for use of the *Wonda Foot Balm* in the treatment of rash, itch, and irritation, and for permanently preventing corns and callouses; of the *Wonda Mineral Foot and Body Bath* and *Wonda Mineral Foot Bath* in the treatment of a rundown condition, inflammation, rheumatic pains, and inflamed and sore swelling feet; and of the *Wonda Stone* in preventing headaches.

DISPOSITION: 9–27–56. Default—destruction.

5287. Watt's Prostatories. (F. D. C. No. 39005. S. No. 18–877 M.)

QUANTITY: 306 pkgs., each containing 27 suppositories, and 554 pkgs., each containing 12 suppositories, at Columbus, Ohio, in possession of Watt's Products Co.

SHIPPED: 11–1–55, from Jersey City, N. J.

LABEL IN PART: (Pkg.) "Watt's Prostatories * * * Active ingredients: Powdered extract of Poke Root (Phytolacca) in a bland emollient base. An aid in the relief of minor discomfort and irritability of the bladder in elderly men. * * * Distributed By Watt's Products Co. Box 666 Columbus 16 Ohio."

ACCOMPANYING LABELING: Leaflet enclosed in each package entitled "Information About Prostatories."

RESULTS OF INVESTIGATION: The above-described label and leaflet were supplied to the shipper by Watt's Products Co., and advertisements headed "Prostate Symptoms" were printed on instructions of the company.

LIBELED: 3–21–56, S. Dist. Ohio.

CHARGE: 502 (a)—when shipped, the name of the article "Prostatories," which represented and suggested that the article was an effective treatment for disorders of the prostate gland, was false and misleading since the article was not an effective treatment for such disorders; and the labeling of the article contained false and misleading representations that the article was effective for the relief of discomfort and irritability of the bladder in elderly men; and 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use in the treatment of prostate symptoms and attendant discomforts.

DISPOSITION: 7–1–57. Default—destruction.

5288. Radiant Health juice extractors. (F. D. C. No. 38475. S. No. 7–735 M.)

QUANTITY: 3 devices at Denver, Colo., in possession of J. M. Newman, t/a Radiant Health Products.

SHIPPED: During 1953 and January 1955, from Bellingham, Wash., and Sierra Madre, Calif., by Radiant Health Products and Stoman Mfg. Co.

LABEL IN PART: (Device) "Radiant Health Unit Model A 110 Volts Radiant Health Products * * * Bellingham, Wash." and "The Juice Queen Model G Radiant Health Products * * * Bellingham, Wash."

ACCOMPANYING LABELING: Leaflets entitled "Juice in a Jiffy," "To All Those Who, Through The Sale Of Vegetable Juicers, Are Attempting To Improve The Health Of This Nation," "The Juice Queen The Juicer you have been waiting for," and "Price List Radiant-Health-Units A and B * * * Directions for use of radiant Health Units . . . . . Models A and B"; Card entitled "Science At Work For Your Health"; booklet entitled "Drinking Vegetables"; and book entitled "What Must I Do?" The labeling was printed locally for the consignee.

RESULTS OF INVESTIGATION: The devices were juice extractors. They were promoted for sale through sales presentations given by representatives of Radiant Health Products, Denver, Colo., at the homes of prospective customers. During the course of a sales talk to an individual, a sales representative made oral representations that the article was an effective treatment for the diseases, symptoms, and conditions described below.

LIBELED: 10–6–55, Dist. Colo.

CHARGE: 502 (a)—when shipped and while held for sale, the name "Radiant Health Unit" appearing on one device, and the firm name "Radiant Health Products" appearing on all of the devices, represented and suggested that the devices were effective for providing radiant health, which names were false and misleading since the devices were not so effective;

502 (a)—the labeling accompanying the devices, while held for sale, contained false and misleading representations that vegetable and fruit juices made with the devices would work wonders in rebuilding the body and overcoming conditions of ill health; and

502 (f) (1)—the labeling of the devices, while held for sale, failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the devices were intended, namely, Bright's disease, liver trouble, arthritis, rheumatism, heart disease, kidney disease, sinus trouble, colds, ulcers, diabetes, hemorrhages, tuberculosis, varicose veins, stomach troubles, hay fever, paralysis of the throat, nervous conditions, polio, worms, pernicious anemia, cancer, and infections of the blood stream.

DISPOSITION: 8–14–56. Consent—claimed by J. M. Newman and Mrs. Laura Newman and released for relabeling. The claimant did not make arrangements for relabeling, and on 8–7–57, the devices were turned over to the Food and Drug Administration.

5289. Low grade uranium ore and thorium ore. (F. D. C. No. 39511. S. No. 27–776 M.)

QUANTITY: 4 tons at Miami Beach, Fla., in possession of Uranium Health Center, Inc.

SHIPPED: The *uranium ore* was transported during November 1955, from Grants, N. Mex., by George Polites and Julian Sedlock, and the *thorium ore* was transported in January 1956, from South Carolina by Julian Sedlock.

RESULTS OF INVESTIGATION: After receipt at Miami Beach, Fla., the ores were blended together and spread into 8 so-called beds consisting of plywood boxes about 6½ ft. long, 2½ ft. wide, and 1 ft. deep. A sheet and a pillow for the patient were placed on each bed.

LIBELED: 10–9–56, S. Dist. Fla.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use in the treatment of arthritis,

bursitis, and rheumatism, which were the purposes and conditions for which the article was intended and was being offered.

DISPOSITION: The Uranium Health Center, Inc., claimant, filed an answer on 10–25–56, denying that the article was misbranded. Subsequently, the deposition of George Polites was taken; and, on 1–16–57, the court granted the Government's motion for summary judgment on the ground that there was no genuine issue as to any material fact. Thereafter, on the same day, the court entered judgment of condemnation and ordered that the article be disposed of in compliance with the law.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

5290. Veratrum viride powder. (F. D. C. No. 39912. S. No. 38–596 M.)

QUANTITY: 2,800 lbs. at Decatur, Ill.

SHIPPED: During 1947, from New York, N. Y.

LABEL IN PART: "Powdered Veratrum Viride."

LIBELED: 1–9–57, S. Dist. Ill.

CHARGE: 501 (a) (1)—contained insects while held for sale.

DISPOSITION: 3–18–57. Consent—claimed by Irwin, Neisler & Co., Decatur, Ill. Segregated; 130 lbs. destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5291. Del-Caps capsules, Del-Bardex #2 capsules, Del-Spas capsules with B-complex, and Del-O-Bex capsules. (F. D. C. No. 39827. S. Nos. 10–264 M, 13–784 M, 14–784 M, 31–845 M, 38–354 M.)

INFORMATION FILED: 1–16–57, N. Dist. N. Y., against Delmar Pharmacal Corp., Rensselaer, N. Y., and Manuel Schindler, president.

SHIPPED: Between 5–27–55 and 6–15–56, from New York to Iowa, Missouri, California, and Pennsylvania.

LABEL IN PART: (Drum) "Del-Caps 15 Timed Disintegration Capsule Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. Caution: Federal law prohibits dispensing without a prescription"; (btl.) "Del-Bardex #2 Timed Disintegration Capsule Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. Amobarbital 100 mg. (Warning: May be habit forming) Caution: Federal law prohibits dispensing without a prescription. 1000 Capsules," "Del-Spas with B-Complex Timed Disintegration Capsule Each Capsule Contains: Phenobarbital ¾ gr. (Warning: May be habit forming) Atropine Sulfate 1/66 gr. Thiamin Hydrochloride 3 mg. Riboflavin 1.5 mg. Niacinamide 15 mg. Calcium Pantothenate 0.9 mg. Pyridoxin Hydrochloride 0.45 mg. Caution: Federal law prohibits dispensing without a prescription. 1000 Capsules," or "Del-O-Bex 7½ Timed Disintegration Capsule Each Capsule Contains: D. L. Amphetamine Sulfate 7½ mg. Thyroid 1½ gr. Atropine Sulfate 1/180 Aloin ⅛ gr. Phenobarbital ⅛ gr. Caution: Federal law prohibits dispensing without a prescription."

RESULTS OF INVESTIGATION: Analyses disclosed that the *Del-Caps capsules* were approximately 17½ percent deficient in dextro-amphetamine sulfate; that the *Del-Bardex #2 capsules* were approximately 24 to 42 percent deficient in dextro-amphetamine sulfate and approximately 20 to 26 percent deficient in amo-

barbital; that the *Del-Spas capsules with B-complex* were approximately 18 percent deficient in phenobarbital; and that the *Del-O-Bex capsules* were approximately 34½ percent deficient in amphetamine sulfate and approximately 11 percent deficient in thyroid.

CHARGE: 501 (c)—the strength of the articles, when shipped, differed from that which they were represented to possess; and 502 (a)—the labeling of the articles, when shipped, contained the following false and misleading representations:

(1) That each *Del-Caps capsule* contained 15 mg. of dextro-amphetamine sulfate;
(2) That each *Del-Bardex #2 capsule* contained 15 mg. of dextro-amphetamine sulfate and 100 mg. of amobarbital;
(3) That each *Del-Spas capsule with B-complex* contained ¾ grain of phenobarbital; and
(4) That each *Del-O-Bex capsule* contained 7½ mg. of amphetamine sulfate and 1½ grains of thyroid.

PLEA: Guilty.

DISPOSITION: 6–4–57. Corporation—$750 fine; Schindler—$350 fine and probation for 2 years.

5292. Halazone tablets and first aid kits. (F. D. C. No. 39419. S. No. 51–893 M.)

QUANTITY: 99 cases, each containing 3 100-btl. ctns., 22 100-btl. ctns., and 150 *first aid kits*, each containing 1 100-tablet btl., at Denver, Colo.

SHIPPED: On an unknown date, from San Diego, Calif.

LABEL IN PART: (Btl.) "100 Water Purification Tablets For Purifying Drinking Water in Canteens Halazone N. N. R. (P-sulfonedichloramido-benzoic acid) * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 45 percent to 110 percent of the declared amount of halazone.

LIBELED: 8–23–56, Dist. Colo.

CHARGE: 501 (b)—the strength of the tablets, while held for sale, differed from the standard for *halazone tablets* set forth in the National Formulary.

DISPOSITION: 1–22–57. Default—destruction.

5293. First aid kits. (F. D. C. No. 39701. S. No. 21–209 M.)

QUANTITY: 252 *first aid kits*, each containing 1 btl. of *Halazone* tablets among other items, at Tulsa, Okla.

SHIPPED: Between 3–28–56 and 6–21–56, from Denver, Colo.

LABEL IN PART: (Btl.) "100 Water Purification Tablets * * * Halazone * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 50 percent to 86 percent of the labeled amount of halazone, whereas the National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 11–21–56, N. Dist. Okla.

CHARGE: 501 (b)—the strength of the tablets, while held for sale, differed from the standard for *halazone tablets* set forth in the National Formulary.

DISPOSITION: 12–7–56. Default—the tablets were destroyed, and the other items in the *first aid kits* were released to the owner.

5294. **First aid kits.** (F. D. C. No. 39427. S. No. 58–361 M.)

QUANTITY: 227 *first aid kits*, each containing 1 btl. of *halazone tablets*, at Denver, Colo.

SHIPPED: 2–16–56 and 7–25–56, from St. Louis, Mo.

LABEL IN PART: (Btl.) "Water Purification Tablets * * * Halazone * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with Sodium Carbonate, Sodium Chloride, and Boric Acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 30 percent to 129 percent of the declared amount of halazone, whereas the National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 8–23–56, Dist. Colo.

CHARGE: 501 (b)—the strength of the tablets, while held for sale, differed from the standard set forth in the National Formulary for *halazone tablets*.

DISPOSITION: 1–22–57. Default—destruction.

5295. **First aid kits.** (F. D. C. No. 39455. S. No. 41–443 M.)

QUANTITY: 116 first aid kits, each containing 1 btl. of *halazone tablets*, at Rochester, N. Y.

SHIPPED: 7–30–56, from New York, N. Y.

LABEL IN PART: (Btl.) "100 Water Purification Tablets * * * Halazone * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with Sodium Carbonate, Sodium Chloride and Boric Acid [or "with sodium borate and chloride"]."

RESULTS OF INVESTIGATION: The *halazone tables* were war surplus stock which had been manufactured in New Jersey and Illinois. Analysis showed that the tablets contained from 29 percent to 88 percent of the declared amount of halazone, whereas the National Formulary provides that *halazone tablets* contain not less than 90 percent of the declared amount of halazone. The tablets in some bottles were stuck together and crumbling, which rendered them unfit for their intended use.

LIBELED: 9–7–56, W. Dist. N. Y.

CHARGE: 501 (b)—the strength and quality of the tablets, while held for sale, differed from the standard set forth in the National Formulary for *halazone tablets*.

DISPOSITION: 10–15–56. Default—destruction.

5296. **Clinical thermometers.** (F. D. C. No. 39392. S. Nos. 17–250 M, 19–556 M, 25–386 M, 29–999 M, 30–447 M, 47–488 M.)

INFORMATION FILED: 2–15–57, E. Dist. N. Y., against Cardinal Thermometer Co., Brooklyn, N. Y.

SHIPPED: Between 4–15–55 and 2–21–56, from New York to Virginia, Ohio, Illinois, Washington, and New Jersey.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind—Oral [or "Stubby"]."

ACCOMPANYING LABELING: Leaflet entitled "Certificate of Accuracy For Clinical Thermometers."

CHARGE: 501 (c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since it purported and was represented to comply with the requirements for accuracy specified in Commercial Standard CS1–52 issued by the National Bureau of Standards of the Department of Commerce, whereas the article failed to comply with such requirements; and 502 (a)—the following statements in the above-mentioned leaflet were false and misleading: "We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce."

PLEA: Guilty.

DISPOSITION: 12–19–57. $300 fine.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE *

5297. Sustamin tablets. (F. D. C. No. 36843. S. No. 80–668 L.)

QUANTITY: 41 display ctns., 6 50-tablet pkgs. each, and 9 display ctns., 6 100-tablet pkgs. each, at Philadelphia, Pa.

SHIPPED: 4–20–54, from New York, N. Y., by Protam Pharmacal Co.

LABEL IN PART: (Ctn.) "Sustamin 2–12 * * * 12 Hour Continuous Medication With Only 2 Tablets * * * New Medical Discovery"; (pkg.) "Sustamin Tablets 2 Tablets – 12 Hour Medication * * * Active Ingredients Each tablet contains Sodium Salicylate Acetophenetidin 2 gr., Anhydrous Caffeine."

ACCOMPANYING LABELING: Circular entitled "Sust-A-Gram * * * New Hospital Proved Sustamin 2–12 Stops Pains of Arthritis-Rheumatism, Bursitis, Neuritis, Sciatica, Lumbago."

LIBELED: 6–23–54, E. Dist. Pa.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, bursitis, sciatica, lumbago, swelling, and inflammation, and for providing increased mobility to impaired joints.

DISPOSITION: On 9–24–54, John T. and Harriet Andreadis, d/b/a Protam Pharmacal Co., filed a claim and an answer denying the misbranding charge above. The Government filed interrogatories on 2–8–55, and the claimant filed objections to the interrogatories on 3–18–55. On 9–30–55, the claimant's objections to certain interrogatories were sustained in part, and the court ordered the claimant to answer the other interrogatories. The claimant filed answers to the interrogatories as ordered; and, on 5–2–56, the Government filed a motion for summary judgment, which was denied on 7–9–56, as the court found that the record showed substantial questions of fact existed.

*See also Nos. 5287, 5288, 5291, 5296.

On 2–4–57, the claimant having previously withdrawn the answer and claim, the court entered a decree of condemnation and destruction.

5298. **30 Plus tablets.** (F. D. C. No. 39251. S. No. 58–581 M.)

QUANTITY: 64 120-tablet btls. at Denver, Colo., in possession of Woodard Laboratories of Colorado.

SHIPPED: On 4–26–56 and 6–4–56, from Hollywood, Calif., by Pacific Mineral Industries.

LABEL IN PART: "30 Plus An Organic Formula Iron, Iodine And Copper in A Special Base Of Mexican Damiana Leaves Honduras Sarsaparilla Root True Cramp Bark – Squaw Vine Black Haw Bark of Root * * * A Dietary Supplement."

ACCOMPANYING LABELING: Circulars entitled "Organic Herbs And Minerals Containing Natural Hormones," "Tired—Run Down—Weak—Listless—Tired Blood Due To Iron Deficiency Anemia * * * Formula 30 Plus," "Look For Nutritional Iron And Iodine Deficiencies," and "Doctor's Order Form."

RESULTS OF INVESTIGATION: The circular entitled "Doctor's Order Form" was printed for the consignee, and the other circulars were shipped to the consignee on various dates by the Pacific Mineral Industries.

LIBELED: 6–18–56, Dist. Colo.

CHARGE: 502 (a)—when the article was shipped and while it was held for sale, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for menopausal symptoms, palpitation of the heart, nervousness, symptoms caused by insufficient hormone production by the body, iron deficiency anemia, and symptoms attributed to iron deficiency anemia.

DISPOSITION: 8–23–56. Default—destruction.

5299. **Radium Stone device.** (F. D. C. No. 39513. S. No. 27–394 M.)

QUANTITY: 36 *Radium Stone devices and accessories* consisting of 72 3-gal. stoneware crocks with spigots and 18 lbs. of ground yellow mineral, at Dallas, Tex., in possession of J. R. Hogan.

SHIPPED: On or about 2–9–56, a quantity of ground yellow mineral was transported from Colorado Springs, Colo., to Dallas, Tex., by J. R. Hogan.

ACCOMPANYING LABELING: Leaflets entitled "Have A Radioactive Spring In Your Home" and "Instructions for Use of Radium Stone."

RESULTS OF INVESTIGATION: After transporting the ground yellow mineral to Dallas, Tex., J. R. Hogan added a portion of the mineral to ready-mixed concrete and made 36 concrete objects in the shape of cone frustums, some of which measured 4 inches in height and 2½ inches in diameter at the base and others 2 inches in height and 3 inches in diameter at the base. Each concrete cone frustum was known as a "Radium Stone," and it purported to produce radioactive water when placed in a 3-gal. crock filled with water. The directions for use provided for drinking not less than 12 glasses a day of the treated water.

Examination showed that the concrete cone frustums and the ground yellow mineral matter emitted slight beta gamma radiation.

LIBELED: 11–2–56, N. Dist. Tex.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was a phys-

ical stimulator to the entire body, would help the body throw off natural waste and activate the metabolic processes, would promote natural functioning of the ductless glands, produce vascular changes in the nervous system, reduce cerebral hypertension, stimulate the sex organs, would act as a diuretic, promote digestion, give increased vigor to all body processess, stimulate intellectual facilities, prevent insanity, promote a healthy brain, retard advance of old age, create a splendid, youthful, joyous life, and destroy disease; that the article was a sure cure for anthrax, typhoid, diphtheria, cancer, neuritis, neuralgia, tumors, and abnormal growths; that the article would reduce high blood pressure and prevent hardening of the arteries; and that the article would prevent tumors, ulcers, cancer, and goiter in children.

DISPOSITION: 12–17–56. Default—a portion of the article was delivered to the Food and Drug Administration, and a number of the stoneware crocks were delivered for use of a Federal institution. The remainder of the article was destroyed.

DRUG FOR VETERINARY USE

5300. Barton's Cannibalism Remedy. (F. D. C. No. 37922. S. No. 8–731 M.)

QUANTITY: 18 cases, 12 cans each, at Lincoln, Nebr.

SHIPPED: During December 1954, from Galesburg, Ill., by Lyles Products Co.

LABEL IN PART: (Can) "Barton's Cannibalism Remedy * * * Ingredients: Special Steamed Bone Meal, Di Sodium Phosphate, Calcium Carbonate, Sodium Sulphate, Potassium Iodide, Charcoal, Manganese Sulphate, Soda Bicarbonate, Flowers of Sulphur, Iron Sulphate, Copper Sulphate, Yeast, Anise, Blood Flour. * * * 2 Pounds Net Weight."

ACCOMPANYING LABELING: Streamers entitled "For Cannibalism Trouble Use The Proven Treatment We Guarantee Satisfaction Barton's Cannibalism Remedy" and circulars entitled "Barton's Cannibalism News."

LIBELED: 4–19–55, Dist. Nebr.; libel amended 11–3–55.

CHARGE: 502 (a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article would overcome cannibalism in poultry.

DISPOSITION: Lyles Products Co., claimant, filed an answer denying that the article was misbranded as alleged. The Government and the claimant served interrogatories upon each other. The Government answered all of the interrogatories served upon it, and the claimant answered some of the interrogatories and filed objections to the remaining interrogatories. The hearing on the objections was held on 8–26–55, and on 8–27–55 the court handed down the following opinion:

DELEHANT, *District Judge:* "The United States, by Libel of Information, seeks, under Title 21 U. S. C., Section 334, to obtain the forfeiture of a designated number of cases and cans alleged to contain quantities of 'Barton's Cannibalism Remedy,' a product designed for use in the feeding of poultry. The designated claimant answers, alleging its interest in the proceeding as the manufacturer and labeler of the product and as the person liable to the possessor for its purchase price if the libel be allowed. The libel of information alleges misbranding through false claims in labeling material.

"Pretrial discovery proceedings provoke this ruling. Plaintiff has addressed certain written interrogatories under Rule 33 of the Rules of Civil Procedure to claimant. Claimant has served and filed formal objections to some of the interrogatories and made answer to others, contending, in fact that it has actually answered all of the interrogatories not specifically objected to.

However, plaintiff has served and filed a motion for an order compelling the claimant 'properly, fully and completely' to answer some of the questions which the claimant contends he has already fully answered. These motions are now considered and ruled upon separately.

CLAIMANT'S OBJECTIONS TO CERTAIN INTERROGATORIES

"Objection is first made to interrogatory numbered 18 which asks for 'the names and addresses of all users of Barton's Cannibalism Remedy, if any, who have indicated dissatisfaction with its use' and the cause of dissatisfaction stated by each. To the extent that the objection insists that the answers called for are matters going to the preparation of plaintiff's case which claimant is not required to furnish and are voluminous and in such detail that they should be covered by a deposition rather than by written interrogatories, the court considers that the objection is clearly unfounded. Presumably, the answer will aid in the preparation of the plaintiff's case, but that is no barrier to its pursuit. Neither is its voluminous character. The objection also argues that the material sought should be gotten under Rule 34. That position misconceives the reach of plaintiff's request. It does not ask for copies or the originals or records or writings. Indeed, the information it seeks is not limited to records or writings, but may even extend to complaints of customers orally made. The court is satisfied that the objection should be, and it is being, overruled in its entirety.

"Claimant then objects to question 20 which asks the names and addresses 'of all persons who have submitted claims against the product liability insurance' for the product. The objection is not too happily framed. It asks that the claimant be relieved of making the answer as not within his knowledge and as a mere conclusion and an attempt by plaintiff to get the names of witnesses. But upon oral argument counsel for claimant advanced a much more cogent reason for the rejection of the question. He pointed out that in his answer to question 19 claimant has declared that there are no insurance companies with which the claimant carries or carried such product liability insurance. That answer is an obvious demonstration that no necessity exists for the making of any answer to question 20. The objection to question 20 is, therefore, being sustained and claimant is being absolved from the necessity of answering it.

"Similarly, the objection to question 31 is being sustained. That question demands the disclosure of 'the names and addresses of the officers of Lyle's Products, Inc.' It is objected to as assuming a fact shown by the pleadings to be untrue. And that objection is well taken, at least so far as the position of claimant is concerned; for he elsewhere takes the position that the designated products company is not incorporated.

"Separate objections are then made to questions 32, 33, 34 and 35 on the ground that each of them is not within the issues of the case. Those questions are very brief and are copied in full as follows:

32. Give the name and address of the printing firm where the streamer and circular named in Interrogatory 1 were printed.
33. How many copies of each were printed?
34. Did Lyles Products Co. place the order or pay for the printing of the streamer and circular named in interrogatory 1?
35. What use did Lyles Products Co. expect would be made of the streamer and circular named in Interrogatory 1?

It is too obvious to require discussion that the material sought in these questions is not beyond the issues of the case, that the questions should be answered and an order to that effect be made.

"Objection is made finally to question 36 which, referring to the circular identified in the several questions last quoted and to certain testimonial letters incorporated therein, demands the name and address of the writer, and the date, of each such letter; whether the claimant has edited any of the letters; and, if so, the verbatim contents of any so edited; the exact location of such letters and the identity and address of the person having custody of them; whether any of the writers of the letters have been or are officials or

employees of Lyles Products Co. and, if so, their respective titles and positions; whether any such writers are friends or relatives of officials and, if so, their identification and the description of their relationship; whether the letters were solicited; whether anything of value was given for them; whether, subsequent to the receipt of such letters, claimant has received any correspondence from their writers and, if so, the exact contents of such letters; the identity of the person who described and prepared a booklet distributed by one Victor Sunwall and the identity of the party or parties who paid for its preparation and distribution. To that question it is objected that it is not within the issues of the case, is an attempt by plaintiff to obtain names of claimant's witnesses, is matter entering into the preparation of the plaintiff's case which claimant is not required to furnish and which, because of its volume and detail, ought to be gotten by deposition, and is also obtainable under Rule 34. The court considers the objection not to be well taken. It may be granted that in large part the material sought might be obtained either by deposition or by motion for production under Rule 34. But that ought not to bar its quest through interrogatories. The court is disposed both to doubt that the work of answering the question will be unduly burdensome, and also to consider that, if it should be thus burdensome, the business of claimant would be even more violently disarranged by the taking of depositions or by compliance with an order under Rule 34. That objection is, therefore, being overruled.

PLAINTIFF'S DEMAND FOR PROPER, FULL AND COMPLETE ANSWERS TO CERTAIN QUESTIONS

"Plaintiff first asserts that questions 2, 3, 4, 5, 7, 8, 11 and 13 are not answered. It would appear that plaintiff is correct insofar only as question 11 is concerned. Questions 2 and 3 are categorically answered. Each of questions 4, 5, 7, 8 and 13 is so prepared that in view of the answer to an earlier question, it does not call for any answer. Therefore, plaintiff's motion is sustained as to question 11, but overruled as to each of the other questions identified in this paragraph.

"It is next asserted that questions 14 (b) and (c) are not answered. That assertion seems to be factually supported and the motion for complete and full answer to those questions is being sustained.

"A dispute exists between the parties touching the answer made to question 14 (a). The question and answer are as follows:

> Question: What is the qualitative and quantitative formula for the Barton's Cannibalism Remedy seized in this action?
>
> Answer: Ingredients listed in your statement—the percentages are not made public property.

It thus appears that while claimant acknowledges that plaintiff has correctly identified the ingredients in the seized product, he regards the quantities of the several ingredients as a trade secret beyond the reach of the interrogatories. The plaintiff is entitled to the information it seeks. But its communication to the plaintiff ought to be so guarded that it will not automatically result in the public disclosure of the formula. Accordingly, the court grants and sustains plaintiff's motion for full and complete answer to question 14 (a), but in its order makes provision that the answer shall be communicated to counsel for the government, but not filed in this action by such counsel or by the plaintiff or anyone in its behalf.

"It is finally charged by plaintiff that claimant's answer to interrogatory 28 is evasive and incomplete. That charge is made in the following setting:

> Question. If the answer to Interrogatory 27 is in the affirmative, explain the physiological actions produced and the effect of these drugs on the afflicted birds.
>
> Answer. It stops their picking.

Now, that answer seems to the court to be neither evasive nor incomplete. It is direct and positive and, so far as the court can perceive, is complete, even if it be not meticulously particularized. Perhaps a more searching and pointed

interrogatory might reach the material which plaintiff seems to desire. If so, that will be material for another day. For the present plaintiff's motion aimed at the answer to interrogatory 28 is denied and overruled."

The claimant filed its answers to the interrogatories as required by the above decision, and on 1-5-56 the case came on for trial before the court without a jury. The trial was concluded on 1-6-56, and the case then was taken under advisement by the court. On 6-26-56, the court handed down the following opinion:

DELEHANT, *District Judge*: "Within the jurisdictional provision of Title 21 U. S. C., Section 334 (a) plaintiff brought this action and filed its Libel of Information praying for the condemnation and forfeiture of the article or property identified and described in the caption. By way of ground for such relief, plaintiff alleged in its Libel of Information, as amended, that the article was a drug within the meaning of the Federal Food, Drug, and Cosmetic Act, and was misbranded when introduced into, and while in, interstate commerce, and was misbranded while held for sale after shipment in interstate commerce within the meaning of Title 21 U. S. C., Section 352 (a), in that its labeling, namely the can label, the streamer entitled 'For Cannibalism Trouble Use the Proven Treatment We Guarantee Satisfaction Barton's Cannibalism Remedy,' and the circular entitled 'Barton's Cannibalism News,' accompanying said article contained statements which represent and suggest that the article will overcome cannibalism in poultry, which statements were false and misleading since the article will not overcome cannibalism in poultry. It was also alleged that the article had been shipped in the described cases in interstate commerce in or about the first part of December 1954, by Lyles Products Company, Galesburg, Illinois, to Fine Line Products Company (Lincoln Hatchery) 101 West P Street, Lincoln, Nebraska, via Burlington Truck Lines, and at the time of the filing of the Libel, was in the possession of such consignee within the then Lincoln Division of this district. (The divisional structure of the district has since been abolished by Act of Congress). Also asserted, but later abandoned, as a ground for the relief sought was misbranding within the meaning of Title 21 U. S. C., Section 334 for failure to bear adequate directions for use. On account of its abandonment, the latter specification will have no consideration herein.

"Upon the order of the court, Writ of Attachment and Monition and Order for Publication was entered; the article was attached at the Lincoln address already given; and service was made of the Libel; and thereafter notice of the proceeding was duly published.

"In due time claimant served and filed an answer, in which he admitted the alleged possession and shipment in interstate commerce of the article, otherwise denied the allegations of the libel, alleged that he was interested in the matter as the manufacturer and labeler, and if the libel were allowed, as one liable to the possessor for the purchase price of the product, and prayed for dismissal of the libel and for costs. Claimant also gave bond in the penal sum of five hundred dollars, as fixed by the court, for the discharge of the attachment.

"After appropriate discovery proceedings and a pretrial conference, the action has been tried to the court; briefs of the parties have been submitted and considered; and the case is ready for final determination by the court. Except in response to the issue of misbranding through false and misleading statements in labeling, the facts are not seriously in dispute. And even upon that issue most of the facts are uncontroverted. The alleged falsehood and misleading character of the statements made in the alleged labeling is denied, and the evidence is in dispute concerning it.

"The facts as found will first be stated.

"The 18 cases, more or less, each containing 12 cans of an article of drug, labeled in part, on each can 'BARTON'S CANNIBALISM REMEDY' which are more particularly described in the Libel of Information, and which were seized pursuant to the Order for Writ of Attachment. Monition and Publication issued in this case, and particularly the product or article itself, were manufactured and packaged by claimant at his factory in Galesburg, Illinois, and, in December 1954, shipped in interstate commerce to Fine Line

Products Company, Lincoln, Nebraska where they were seized under the Writ of Attachment herein while being held and offered for sale by Fine Line Products Company.

"Upon each of the cans included in the shipment, containing the product or article was posted a paper label on which was printed in attention challenging letters in two colors the words, figures and drawing set out in footnote.[1]

"In each of the 18 shipping cases containing 12 cans of Barton's Cannibalism Remedy there was enclosed at the factory and at the time of and during, and accompanying, the shipment an advertising poster printed in large red characters of varying sizes and emphasis. Each such poster contained the following language in capital letters:

FOR CANNIBALISM TROUBLE

USE THE PROVEN TREATMENT

WE GUARANTEE SATISFACTION

BARTON'S

CANNIBALISM REMEDY

Of the letters on that poster those in the first line were $15/16$ inch high[2]; those in the second and third lines $7/16$ inch high[2] but with an emphasizing thickness of portions of the letters in the third line; and those in the last three lines, reflecting the product's name two inches high.

"In each of the 18 shipping cases containing 12 cans of Barton's Cannibalism Remedy there were enclosed at the factory and at the time of and

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[1] BARTON'S

CANNIBALISM REMEDY

At this point appears a fairly large drawing in outline of an adult chicken immediately above whose head are five detached red reproductions of the character "$" and three drawings to suggest paper currency on the face of one of which are also two smaller red reproductions of the character "$".

LYLES PRODUCTS COMPANY
246 South Seminary Street
Galesburg, Ill.

DIRECTIONS

(Punch out perforated section in top of can)

Spread generous quantity of Barton's Cannibalism Remedy on top your poultry feed. Have a fine layer or film of Barton's Cannibalism Remedy covering the top of all your feeders. When you are experiencing a serious outbreak of Cannibalism use generously at each feeding.

Use Barton's Cannibalism Remedy every few days in your feeding operations, adding one pound Barton's Remedy to each 100 pounds feed.

SATISFACTION GUARANTEED OR YOUR MONEY REFUNDED

Ingredients:

Special Steamed Bone Meal, Di Sodium Phosphate, Calcium Carbonate, Sodium Sulphate, Potassium Iodide, Charcoal, Manganese Sulphate, Soda Bicarbonate, Flowers of Sulphur, Iron Sulphate, Copper Sulphate, Yeast, Anise, Blood Flour.

RECOMMENDED BY HATCHERIES AND POULTRY RAISERS FOR USE AMONG ALL AGE POULTRY FLOCKS

2 pounds net weight

[2] Both of these measurements are made by the judge. And it is at least arguable that instead of the two fractions indicated the correct measurements should be one inch and one-half inch respectively. The indicated fractions have been used because the one inch and one-half inch measurements seem to be very slightly, if perhaps unintentionally, excessive.

during and accompanying the shipment three identical advertising sheets of each of which a copy is reflected in footnote.[3]

"On March 3, 1955, inspector James E. Anderson, an employee of the United States Department of Health, Education and Welfare, Food and Drug Administration, obtained from Fine Line Products Company in Lincoln, Nebraska, as samples for inspection and analysis, two 2-pound unopened cans of Barton's Cannibalism Remedy, a part of such shipment, which was there being held for sale, and forwarded them to the laboratories of said Food and Drug Administration at St. Louis, Missouri, for analysis. The contents of such cans consisted of a gray and white powdered material having the odor of Anise. The contents of the entire lot of 18 cases each containing 12 cans of Barton's Cannibalism Remedy, so seized, were identical with the contents of those samples so taken by Anderson.

"The sample above referred to was forwarded by inspector Anderson to such laboratories where the cans were opened and the contents qualitatively and quantitatively analyzed by Harold E. Theper, a qualified analytical chemist in the employ of such Food and Drug Administration, under the supervision of Curtis R. Joiner, Chief Chemist, and Roy S. Pruitt, Chief Chemist, St. Louis, Missouri. Reproduced in a footnote [4] are excerpts from the

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[3] BARTON'S CANNIBALISM NEWS—
Vol. 2, No. 1
Galesburg, Illinois, U. S. A. 1954
Published by Lyles Products Company, 246 S. Seminary
Galesburg, Illinois
Owners and Nation-wide Distributors of BARTON'S CANNIBALISM REMEDY
Barton's Cannibalism Remedy Advertisements Have Appeared in
These Nation-Wide Publications—
Here appear reproductions of the cover sheets of six magazines, including:
HATCHERY AND FEED
POULTRY SUPPLY WORLD
FARM JOURNAL
CAPPER'S
AMERICAN POULTRYMAN
POULTRY TRIBUNE

GUARANTEED RESULTS

Every can of Barton's Cannibalism Remedy is unconditionally guaranteed to produce good results or your money cheerfully refunded by the retail dealer.

This guarantee is fully backed by Lyles Products Company to insure complete customer satisfaction.

[Here appears a reproduction of a can supposedly containing Barton's Cannibalism Remedy, with a label showing the last portion of what is copied in Footnote 1.]

Of the foregoing advertising sheet the separate lines "BARTON'S CANNIBALISM NEWS" and "GUARANTEED RESULTS" with the horizontal lines immediately above and below the latter are in red capital letters. All of the rest of the printed language and drawings are in black, with the letters of different sizes and type styles, some of them capitalized, others not.

[4] Laboratory conclusions—
(See attached for report of examination)
Sample is a dry mixture that contains chloride equivalent to 2.86% NaCl; sulfates, phosphates, bicarbonates and/or carbonates of sodium, manganese, iron and calcium; sulfur and anise.

REPORT OF EXAMINATION

Commodity code 42.2—Product Barton's Cannibalism Remedy Sample No. 8–731 M
Description of sample—Two packages wrapped in brown kraft paper and sealed "8–731 M 3/3/55 James E. Anderson," containing one carton each, carton identified "8–731 M 3/3/55 James E. Anderson."
Product: Gray and white powdered material, having odor of anise.
Container: Cylindrical cardboard container, with metal shaker top and metal friction close bottom.
Labeling: Label on container—Two circulars from shipping cases and labels on shipping case submitted by inspector.
Net Contents: Declared 2 lbs.
Examination:
Soluble Chloride calculated as Sodium Chloride—2.86% (A. O. A. C. 22.64–22.65)

(Footnote 4 continued on p. 210.)

report of the qualitative analysis so made. And reproduced in a further footnote[5] is the essential, and much the greater, part of the report of the quantitative analysis so made.

Qualitative tests:
Portion of sample water extracted:
Sulfate—ppt. with $BaCl_2$—positive
Sodium—flame test—positive
Chloride—ppt. with $AgNO_3$—positive
Portion of sample extracted with acid:
Phosphate—ppt. with Ammonium molybdate—positive
Calcium—ppt. with Ammonium oxalate—positive
Iron—color with thiocyanate—positive
Manganese—color developed by sodium bismuthate—positive
Carbonate (and/or) bicarbonate—effervescent with acid—positive
Sulfur—characteristic odor on ignition—positive
Anise—odor apparent.

[5] REPORT OF EXAMINATION

Commodity code 42.2—Product Barton's Cannibalism Remedy

Sample No. 8–731 M

Mfr.-Shipper: Lyles Products Company, Galesburg, Illinois.

Description of sample Two packages, one sealed "8–731 M 3–14–55 Harold E. Theper" and both with original seals (One package with original unbroken seals).

These additional analyses were made because of Division of Regulatory Management's letter of 5/24/55.

Analysis: General Analysis

Water Soluble material (Calculated by subtracting water insoluble material from 100%).	13.20%
Water Insoluble material (0.5000 g. triturated in water and insoluble material filtered off, dried @ 100° C and weighed).	86.80%
Acid Insoluble Material (1.0000 g. boiled in 1+1 HCl, diluted with hot water, filtered, dried @ 100° C and weighed).	11.79%
Water Insoluble, Acid Soluble Material (Calculated by difference between Water Insoluble material and Acid Insoluble material).	75.01%

Specific Analysis

Loss on drying @ 100° C for 2 hrs.	1.29%
pH of water solution (2 g. in 50 ml.)	5.5
Calcium Phosphate $Ca3(PO_4)_2$, a measure of the bonemeal present, calculated from detn. of total acid soluble phosphates, pptn. & titn. of ammonium-phospho-molybdate	10.90%
Calcium Carbonate ($CaCO_3$) Calculated from difference between total calcium and calcium phosphate detn. calcium pptd. as oxalate and detd. volumetrically with $KMnO_4$. (Check detr. by CO_2 evolution, 56.33%).	55.44
Sodium Chloride (NaCl) (Calculated from water soluble chlorides detn. by pptn. with silver nitrate and weighing and correction for Iodine).	2.92%
Check detn. by A. O. A. C. 22.64–22.65	2.92%
Sulfur (S) (Acid insoluble residue treated with carbon disulfide and extract evapd. and weighed after drying @ 100° C).	5.87%
Charcoal (C) (Loss on ignition on material insoluble in carbon disulfide and acid).	5.71%
Ash on material insoluble in acid and carbon disulfide	0.23%
Iron Sulfate (Ferrous sulfate, anhydrous). (Calculated from total acid soluble iron detd.—reduction with $SnCl_2$ and Zimmerman Reinhardt titration ($KMnO_4$) method)	0.48%
Manganese Sulfate ($MNSO_4$) (Detd. by oxidation with sodium bismuthate and reduction of permanganic acid with ferrous sulfate).	0.03%
Copper Sulfate ($CuSO_4$) (Copper sep. by ppt. with H_2S and detd. by iodometric titn.).	0.02%
Potassium Iodide (KI) (Iodine detd. by U. S. P. Thyroid method and calc. as KI).	0.026%
Sodium Sulfate (Na_2SO) (Total acid soluble sulfates detd. by ppt. with Barium chloride. Sodium sulfate calculated after corrections for sulfate from manganese, copper and iron).	4.54%
Sodium Bicarbonate ($NaHCO_3$) Water extract did not effervesce and pH of extract too high for it to exist in solution. No evidence of its presence indicated by CO_2 evolution.	None found
Di Sodium Phosphate (Na_2HPO) Water soluble portion gave no ppt. with ammonium molybdate.	None found
Other declared ingredients Yeast. Blood flour and anise oil were not determined. (Total of ingredients for which analysis was made Yeast determined to be present by microscopic examination.	87.46%)

(Footnote 5 continued on p. 211.)

"The foregoing facts are found upon the basis of a written stipulation, upon which in substantial part the case was tried. Upon the faith of the agreement in the same stipulation that 'Harold E. Theper, if called as a witness at the trial and sworn, would testify that he personally made the analyses' above referred to, 'that said analyses were made in strict accordance with standard and approved methods and practices described on said reports, and that the results as shown thereon are true and accurate; and this stipulation may be received and considered by the court in lieu of said witness,' the court considers the analyses as if Theper had so testified. And, the analyses being otherwise unchallenged, the court finds that the reports of them in their entirety, without limitation to the portions thereof preserved by the court in footnotes 4 and 5 hereof are true, exact and correct.

"From the testimony, some of which is conflicting, and from interrogatories propounded, answered, and offered and received in evidence, the following further facts are found to be true.

"The claimant is, and at all material times was, an individual, residing and engaged, under the name and style of Lyles Products Company, in business, in Galesburg, Illinois. He operates there a wholesale grocery business. For an inexactly defined period, but somewhat more than four years, he has also marketed a product which he sells as, and represents to be, a remedy for the destructive practice among chickens, which, from its nature and results, has come to be known as cannibalism.[6] He causes this product to be manufactured for him, according to a formula which he has devised, principally by a stock feed manufacturer at Marseilles, Illinois, but partly also, though in what proportion is not clearly shown, by another maker. It is shipped to him at Galesburg in one hundred pound bags or sacks. In his Galesburg plant, claimant merely opens the bags and repackages the product in his own labeled two pound cans; and he ships the product thus repackaged upon orders from customers.

"Originally claimant applied to the product the name 'Barton's Cannibalism Cure.' In 1953 the Food and Drug Administration of the United States questioned his right to use that name, and at first took particular exception to the word 'Cure.' Thereafter, claimant abandoned the use of that word and marketed the product under the name 'Barton's Cannibalism Remedy' by which name it was being sold when this action arose. While claimant as a witness undertook to give the impression that the use of the word, 'Remedy' was initiated and made with the approval of the Food and Drug Administration, the court finds that no such approval was given. Claimant with some imprecision refers such supposed approval to a conference he had on July 30, 1953 with the already mentioned Chief Chemist, Pruitt, at the Administration's regional office in St. Louis, Missouri. But it is satisfactorily demonstrated and found that administrative approval was not then given of the use of the name, Barton's Cannibalism Remedy. The Conference was held after the transmittal under date of July 14, 1953 by the Administration's St. Louis District office to claimant of a charge sheet in which the Administration had taken the position that the product was not an effective treatment for cannibalism in poultry, and was, therefore, misbranded when referred to as Barton's Cannibalism Cure. The result of the conference was indecisive and on its close, the matter was, by the Administrator placed in permanent abeyance on the promise of claimant to make a satisfactory revision of his labels. But claimant was not notified of that action. At about, or shortly after the conference, claimant began to identify his product as Barton's Cannibalism Remedy and about September 26, 1953, sought approval of a proposed label bearing that

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Description of sample

LABORATORY CONCLUSION

Product is a grey powdered mixture containing chiefly Calcium, Carbonate, Calcium Phosphate, sodium sulfate, charcoal, sulfur, salt, and small amounts of manganese, iron, copper, potassium iodide, yeast and anise.

[6] Concerning the characteristics and classification of which see discussion, infra.

name. But on October 6, 1953 the Assistant to the Commissioner by a letter fully copied in a footnote[7] disapproved of the proposed name and label. Despite such disapproval the name was, and thereafter has been, used by claimant and was used in the labeling against which this proceeding is named.

"The product contains the ingredients identified upon the can labels and appearing in the caption hereto. This is found to be true despite the failure of the quantitative analysis (see footnote 5) to identify among those ingredients those named as Di Sodium Phosphate, Soda Bicarbonate, Anise, and Blood Flour. But claimant has not favored the court with a disclosure of the proportions in which those ingredients are mixed into the whole mass.

"Claimant's principal manufacturer of his product also makes and bags a product to which it applies the name, VITEM, which contains essentially the same ingredients as those in claimant's product.[8] With identical proportions of its ingredients, VITEM is marketed as a meal form 'digester and balancer A vitamin re-inforced feed' (a) for hogs and (b) for sheep and cattle. For sheep and cattle it is also marketed with somewhat less calcium and common table salt, and very slightly more Phosphorus. Claimant's product is, therefore, essentially indistinguishable from a general stock feed. It is true that as a witness claimant declared that there were some proportional disparities in ingredients as between his ingredients and VITEM. But he did not point them out, in fact said that he could not, and the court does not find that such disparity actually exists, or if it does what its extent is and whether it results in any real distinction between the products.

"Cannibalism in poultry is a disordered condition in which an affected bird within a flock develops the aberration of picking at other birds in the flock. The practice varies from a mild picking to the extremity in which the picking bird destroys the bodily tissue of, and actually eviscerates, its victims which it eats to some extent. It is, in point of fact, a disease with which the cannibal bird is afflicted.[9]

"Many factors may conspire to introduce cannibalism into a flock of chickens. Among these are overcrowding of the birds, excessive heat in their enclosure, excessive light, unsanitary housing facilities, inadequate litter, lack of scratch feed, inadequate feeding and watering area, and improper diet. In a general manner of expression it arises in the first instance from poor husbandry in the poultry field.

"Veterinary science has not, thus far, come upon any chemical or drug formula which will eliminate or correct the malady. The best corrective results, saving extreme and persisting cases, have been obtained from the resort to good husbandry in the management of flocks, including particularly the elimination of the foregoing causative or predisposing factors. But such improvements do not invariably eliminate the practice, and despite them, many birds persist in it. In such cases picking can be and is physically prevented, often by the use of physical barriers to it, such as protective shields for the

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[7] OCTOBER 6, 1953.

LYLES PRODUCTS COMPANY, INCORPORATED,
Attention Mr. R. Lyle Barton,
246 South Seminary Street,
Galesburg, Illinois.

GENTLEMEN: We have your letter of September 26 enclosing the proposed label for Barton's Cannibalism Remedy.

As was pointed out in the charge sheet sent you on July 14, 1953, by our St. Louis district, we think the article is not an effective treatment for cannibalism in poultry. For this reason, we think the name "Barton's Cannibalism Remedy" causes the article to become misbranded under the Federal Food, Drug, and Cosmetic Act.

It is suggested that if you correspond with us again on this subject you inform us as to the identity and proportion of each ingredient used in the manufacture of the article, and pro ide your basis for thinking that any particular purpose is served by feeding an article of this unusual composition to poultry.

Sincerely yours,

M. L. YAKOWITZ,
Assistant to the Commissioner.

[8] This is found upon the basis both of claimant's statement to that effect as a witness and of labels for VITEM received in evidence which disclose its ingredients. They seem to vary from those in claimant's product in these respects. VITEM is not said to contain Di Sodium Phosphate, but the record fails to disclose whether and how far that omission alters its essential character. And VITEM professes to contain Sodium Chloride, not listed among the ingredients of claimant's product. But, as appears from footnote 5, the latter product actually contains Sodium Chloride.

[9] See discussion later in memorandum.

victim birds and blinders upon the pickers. But these are cumbersome and only partially satisfactory. The most effective control is achieved by 'debeaking' the offending members of a flock. That consists of the surgical removal of a substantial share of the frontal part of the bird's upper beak. Without the removed segment it can not effect a real bite.

"Cannibalism afflicts younger birds at all stages of their growth. It is found among baby chicks, also among flocks of pullets and sometimes among laying birds. Each group has to be dealt with according to its age.

"Barton's Cannibalism Remedy is not in truth a remedy for cannibalism. It does not, nor could its published ingredients in the proportions found in it or in any reasonably conceivable proportions, prevent, cure, arrest or correct the practice of cannibalism.[10]

"The labeling of the seized product which accompanied it upon its introduction into and on its course in interstate commerce and was with it while, after its shipment in interstate commerce, it was held for sale, was and is false and misleading.

"In the present context and within the definition and meaning of the Food and Drug Act, Barton's Cannibalism Remedy is a drug.

"Of the factual findings more recently set out, some involve or imply legal conclusions. They are, accordingly, intermingled findings of fact and conclusions of law. That is not an unusual situation. Findings have frequently to be made upon facts in issue, which rest both upon actual events and upon the consequences which legally follow from them. The court has then to pronounce upon matters that lie in a twilight area, of which, on the one side everything is pure fact, on the other all is pure law but whose own components partake of the nature of both. So, in this case, discussion should be offered upon the legal ingredients of some of the announced facts.

"The court has found that, in poultry, cannibalism is a disease. Claimant earnestly contends to the contrary. He does not, and need not, precisely classify or characterize it. The burden lies the other way. The pertinence of the finding readily appears from the following language in Title 21 U. S. C., Section 321 (g):

> *The term "drug" means* (1) articles recognized in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) *articles intended for use in the* diagnosis, *cure mitigation, treatment, or prevention of disease in man or other animals;* and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); . . . . [Emphasis added.]

" 'Disease' is not a narrow term. It is widely comprehensive. Webster's New International Dictionary (1925) defines it thus:

> Lack of ease; discomfort; uneasiness; trouble; vexation; disquiet.
> Med. An alteration of the state of the body or of some of its organs, interrupting or disturbing the performance of the vital functions . . . .; any departure from the state of health presenting marked symptoms . . . malady; affection; illness; sickness; disorder.
> A derangement or disorder of the mind, moral character and habits.
> Syn: Disorder; distemper, ailment; affection.

"To the affirmance of a diseased status it is not imperative that one be afflicted with a common and conventional malady. He is diseased if, through bodily or mental inbalance his normal functioning has been interrupted or perverted. And the disorder may exist as well in the mind or in the nervous system as in the more readily discernible parts of the body. *Chapman v. Finlayson Lease* (Ariz) 107 P. (2) 196; *Lewis v. Liberty Industrial Life Insurance Co.* (La. Ap.) 166 So. 143. Thus, while an evil habit is not inevitably the badge of disease, it is a disease if it has so far fastened itself upon a person as

[10] This was the point most sharply disputed upon the trial. See its discussion in this memorandum, infra.

to render him unable to cope with it. Such in character is an addiction to narcotics or to alcohol. An isolated dalliance with either may be an indiscreet act of a healthy person. Compulsive subjection to its use is surely a disease. *Knowlton v. John Hancock Mutual Life Insurance Co.* (Me.) 79 A (2) 581.

"And the foregoing reflections are equally, if not more, applicable to animals other than man. Our human kind misbehaves voluntarily and responsibly under the guidance of a reasoning intellect and with the assent or spur of an unfettered will. Our lawless conduct is, therefore, generally, though not invariably, quite consistent with sound health. The lower animal, on the other hand, acts involuntarily, upon impulse or instinct peculiar to its kind. Generally, a domesticated animal behaves in an orthodox pattern. Viciousness in it is attributable to some disorder, disturbance, or want of balance. It is so with cannibalistic chickens. They embark upon the bad practice only after their surroundings have materially unsettled their nervous systems, upset them, and impelled them to this unnatural behavior. They do it because they have, in the strictly etymological sense of the term, become 'diseased.'

"It may be observed in passing that claimant's own choice, from time to time, of names for his product puts him at a disadvantage in his insistence that cannibalism is not a disease. He first called it a 'cure,' later a 'remedy,' each a term which is familiarly associated with the alleviation or elimination of disease. Of similar import is the claim that the product is a 'proven treatment.'

"The court, within the definition of the quoted section of the statute, also finds that the seized product is a 'drug.' It was packaged, shipped in interstate commerce, and held for sale, not as a stock feed, but as a *remedy* for cannibalism. In one piece of display material, claimant 'guaranteed results'; in another he spoke of the product as a 'proven treatment,' supra. The term, remedy, connotes the capacity to relieve or mitigate in greater or smaller measure, and in some, though not all, instances completely, a diseased condition. *Sebrone Co. v. Federal Trade Commission* (7 cir) 135 F. (2) 676; *Simpson v. United States* (6 cir) 241 F. 841; *United States v. Natura Co.* (D. C. Cal.) 250 F. 925. And that term appears not only in the advertising but in the very name selected by claimant for the product. The representation that it is a 'proven treatment' brings the product within the literal wording of the statute, for 'treatment . . . of disease' is one of the intended uses any of which makes an article a drug. It may also be noted that in the first numbered paragraph of the factual stipulation already mentioned, the parties refer to the product as 'an article of drug.'

"Another section of the statute, Title 21 U. S. C., Section 321 (k) may be quoted. In part, it is:

> The term "label" means a display of written, printed or graphic matter upon the immediate container of any article;

And subsection (m) of the same section follows:

> The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

It is, therefore, necessarily concluded that, not only the 'label' affixed and adhering to each can, but also both the streamers and the circulars which accompanied the shipment, and each of the several cases therein, must be included within the definition of, and considered to be 'labeling' for the purposes of the case.

"The charge made against the product is that it is misbranded. Under Title 21 U. S. C., Section 352 (a),

> A drug . . . shall be deemed to be misbranded—
> (a) If its labeling is false or misleading in any particular.

"The court has already found as a fact that such labeling was false and misleading. Admittedly that finding is based upon disputed testimony, and

the court recognizes that the burden of proving the disputed fact by a preponderance of the evidence rests upon plaintiff. It may be stated very simply that the court considers that burden fully to have been carried.

"The nature of the claims of the labeling in suit is very direct and simple. It is that the packaged product is a 'remedy' and a 'proven treatment' for poultry cannibalism, satisfaction in the use of which is guaranteed. As has already been made plain, the court finds the claim of the labeling to be both false and misleading, and makes that finding upon the basis of obviously conflicting testimony. The testimony ought very briefly to be recalled.

"In part, it was based upon observations of the practical use of the product, made and offered upon the trial by persons not shown to have had any scientific training or education. For the government two persons testified to their use of the product in chicken flocks of their own, that were addicted to cannibalism, and stated that it had no effect in the way of elimination or amelioration of the malady. Each of these users was a small operator having only a few hundred birds; one was a farm wife living in south central Nebraska, the other a man living in Texas. For claimant there were also two witnesses each of whom testified that observation of cannibalistic chickens into whose ration the product had been introduced showed early and marked abatement, and even cure of the practice. Those witnesses were the claimant himself who testified upon the basis of his observations of some flocks with which he was familiar, and the operator of the large commercial hatchery in which the product was seized. She is also an agent for the sale of the product. The court recognizes that claimant and his supporting witness present a wider base of use and observation than the two lay witnesses for the libelant. But claimant and the hatchery operator are manifestly strongly interested witnesses.

"But besides that 'practical' testimony the libelant produced very substantial and creditable testimony from scientifically trained experts; and claimant offered no evidence at all of that character. Those scientific witnesses for libelant presented unusually high educational qualifications for testimony in the field involved. One is professor of poultry disease research at Iowa State College, a Doctor of Veterinary Medicine and the holder of graduate degrees as Master of Science and Doctor of Philosophy in the field of Poultry diseases. Another is a practicing veterinarian in Iowa after a four year course in Veterinary Medicine at Iowa State College. The third is professor of animal pathology and hygiene at University of Nebraska, holding the degree of Doctor of Veterinary Medicine from Iowa State College and the graduate degrees of Master of Science and Doctor of Philosophy in comparative pathology from the University of Minnesota, who for four years studied under a fellowship in comparative pathology at Mayo Foundation, Rochester, Minnesota. Both their educational foundation and their manner of testifying were impressive. In short, they testified unequivocally that the product in suit, with its ingredients in any combination, is, and would be, wholly ineffective as a remedy or corrective of cannibalism in chickens. And there is significance in the circumstance that there is no scientific testimony to the contrary.

"Upon the whole testimony the court finds that the evidence overwhelmingly preponderates, in fact shows beyond doubt, that the product is not a 'remedy' or a 'proven treatment' for cannibalism in poultry. That finding is so clearly established as to be factually certain and to be quite beyond the area in which there is a mere difference of scientific opinion.

"Thus, claimant's citation of *United States v. Johnson* 221 U. S. 488 is not instructive. Incidentally, his quotations seem to have been taken from the dissenting opinion of Mr. Justice Hughes, though it would appear that the prevailing opinion of Mr. Justice Holmes might better have supported his position. In this connection, are also the unanimous opinion of the court by Mr. Justice Hughes in *Seven Cases of Eckman's Alternative v. United States* 239 U. S. 510, arising under the act as amended in 1912 after the ruling in the *Johnson* case, supra, and the opinion of Judge Joyce in *United States v. Seven Jugs of Dr. Salsbury's Rakos* (D. C. Minn) 53 F. Supp. 746.

"The court, accordingly considers and holds that the libelant is entitled to judgment for the forfeiture of the seized articles or product, and to the recovery of costs.

"Counsel for the government will prepare forthwith a judgment accordingly, and will submit it to counsel for claimant for approval as to form or for suggested amendment or correction, and upon approval to the court for entry. If amendment or correction be suggested the conflicting positions of counsel will be presented to the court for settlement. The judgment shall speak not as of this date, but as of its signature and filing.

"The clerk will transmit forthwith by United States mail copies of this memorandum to counsel in the proceeding."

Pursuant to the above opinion, judgment of condemnation and destruction was entered on 6–29–56.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5281 TO 5300

PRODUCTS

[1] (5300) Seizure contested. Contains opinions of the court.

[2] (5289, 5297) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5300) Seizure contested. Contains opinions of the court.
[2] (5289, 5297) Seizure contested.

U. S. GOVERNMENT PRINTING OFFICE: 1958

D. D. N. J., F. D. C. 5301–5320 Issued December 1958

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5301–5320

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation; (2) criminal proceedings terminated upon a plea of nolo contendere or guilty or upon a verdict of guilty; and (3) injunction proceedings terminated upon the granting of a motion for summary judgment. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation; the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations; and the injunction proceedings are against the Government.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 4, 1958.*

CONTENTS

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5301–5320

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of penicillin, chlortetracycline, or Chloromycetin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

Publicity, Section 705 (a), the Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof; Section 705 (b), the Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5301. Various drugs. (F. D. C. No. 39209. S. Nos. 23–845/6 M, 30–305 M, 31–774 M.)

INFORMATION FILED: 12–26–56, N. Dist. Ill., against Medical Chemical Corp., Chicago, Ill., and Bernard B. Speiser, president.

SHIPPED: Between 7–2–55 and 9–17–55, from Illinois to Arizona, Indiana, and Tennessee.

LABEL IN PART: (Vial) "Intramuscular–10 cc-Shake Well Triple Hormone Suspension Each cc Contains—Esterone U. S. P. 6 mg.–Testosterone U. S. P. 25 mg.–Progesterone 5 mg.–Pectin 0.35%–Thimerosal 1: 20,000–Sodium Acetate 0.8% Distributed by Myers-Carter Labs., Inc. * * * Phoenix, Arizona," "Sterile Multiple Dose 10 cc Progesterone U. S. P. 50 mg/cc In Buffered Aqueous Suspension Pectin 0.2%–Thimerosal 1: 20,000 Intramuscular Myers-Carter Laboratories, Inc. Phoenix, Arizona," and "Sterile 10 cc Vial Testosterone U. S. P. 50 mg/cc In aqueous suspension Sod. Acetate 0.8%–Pectin 0.35% Thimerosal 1: 20,000 Intramuscular Average Dose: 25 mg. Mfg'd for G and G Pharmacal Co. Inc. South Bend, Ind."; (ampul) "A–50 10 cc. Calcium Gluconate U. S. P. 10% Solution W/V in ampul water no

preservative Intramuscular and Intravenous Morton Pharmaceuticals Inc. Ethical Distributors Memphis, Tenn."

RESULTS OF INVESTIGATION: Examination of the *calcium gluconate* showed that it was pyrogenic and that the other drugs involved were not sterile as represented but were contaminated with viable micro-organisms.

CHARGE: 501 (c)—the purity and quality of the *triple hormone suspension* and the *testosterone*, when shipped, fell below that which they purported and were represented to possess; 502 (a)—the labels of the *progesterone* and *testosterone*, when shipped, contained false and misleading statements that the articles were sterile; and 502 (j)—when shipped, the *calcium gluconate* was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Usual Dose: Adults, intravenous or intramuscular 1 Gram daily or on alternate days; for children, intravenous 0.02 to 0.5 Gram."

PLEA: Nolo contendere.

DISPOSITION: 5-29-57. $1,250 fine, plus costs.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5302. Pega Palo vine and root. (F. D. C. No. 40131. S. No. 70-865 M.)

QUANTITY: 7 bags, ½ oz. each, and 1 bag, containing ¼ oz., of *Pega Palo vine*, and 1 ctn., containing 11 lbs. 9 oz., of *Pega Palo root*, at Iowa Falls, Iowa, in possession of Richard H. Snook, d/b/a Competition Chemicals.

SHIPPED: During January 1957, from the Dominican Republic and Haiti, by Richard H. Snook.

ACCOMPANYING LABELING: Leaflets entitled "Pega Palo Vines and Roots (Fortidom)" and reprints entitled "Pega Palo The Vine That Makes You Virile."

LIBELED: 4-8-57, N. Dist. Iowa.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to 505 (b) was not effective with respect to such drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 5-20-57. Default—destruction.

5303. Pega Palo vine. (F. D. C. No. 40123. S. No. 54-372 M.)

QUANTITY: 439 cellophane envelopes at Yakima, Wash.

SHIPPED: 2-14-57, from Chicago, Ill., by A-1 Import Co.

ACCOMPANYING LABELING: Reprints of an article from the January 1957 issue of "Confidential" magazine entitled "Pega Palo The Vine That Makes You Virile" and leaflets headed "Pego Palo Vine Directions For Use."

RESULTS OF INVESTIGATION: The reprints were shipped from Chicago, Ill., by A-1 Import Co., and the leaflets were printed locally.

Examination showed that the article was a dried, woody, vine-like material.

LIBELED: 4-10-57, E. Dist. Wash.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the drug was intended; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since

an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 7–26–57. Default—destruction.

DRUGS FOR VETERINARY USE

5304. Animal feeds containing diethylstilbestrol. (F. D. C. No. 39063. S. Nos. 40–624/5 M, 40–627/9 M, 40–631 M.)

QUANTITY: 127 50-lb. bags of *Cattle Concentrate*, 134 50-lb. bags of *Cattle Concentrate pellets*, and 99 50-lb. bags of *Purdue Supplement pellets* at Quimby, Iowa, in possession of Simonsen Mill-Rendering Plant.

SHIPPED: The articles contained diethylstilbestrol, which had been shipped on 1–10–56, from New York, N. Y.

LABEL IN PART: "Simonsen Cattle Concentrate * * * Stilbestrol Special Mix * * * Each 1 pounds [or "1½ pounds"] contains 10 milligrams of Diethylstilbestrol," "Simonsen Cattle Conc. Pellets * * * Stilbestrol Special Mix * * * Each 2 pounds [or "1½ pounds"] contains 10 milligrams of Diethylstilbestrol," and "Simonsen Modified Purdue Supplement * * * Pellets * * * Stilbestrol Special Mix * * * Each 1 pounds [or "1½ pounds"] contains 10 milligrams of Diethylstilbestrol."

RESULTS OF INVESTIGATION: The articles were manufactured by Simonsen Mill-Rendering Plant at Quimby, Iowa, using the diethylstilbestrol which had been shipped as described above.

LIBELED: 5–7–56, N. Dist. Iowa.

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from that requirement.

The articles, by reason of the presence therein of the active ingredient, diethylstilbestrol, which had been shipped in interstate commerce, were new drugs within the meaning of the law; and an application filed pursuant to law was not effective with respect to the drugs.

DISPOSITION: 6–28–56. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5305. Tetracycline hydrochloride tablets and capsules. (F. D. C. No. 40171. S. Nos. 67–507/8 M.)

QUANTITY: 3 200-tablet btls. and 1 100-capsule btl. at Silver Spring, Md., in possession of Medical Supplies, Inc.

SHIPPED: From New York, N. Y.

LABEL IN PART: (Btl.) "Tetracycline Hydrochlor. [or "Hcl."] * * * 250 mg."

RESULTS OF INVESTIGATION: A sales representative of the manufacturer delivered in person to the consignee sample bottles of 8 tablets or capsules. The sales representative had received the articles from New York, N. Y., and the consignee had repacked into bottles and relabeled the tablets and capsules described above. Neither of the repacked lots had been certified.

LIBELED: 4–24–57, Dist. Md.

CHARGE: 502 (l)—the article, while held for sale, was a drug composed in part of tetracycline, a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 5–22–57. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5306. First aid kits. (F. D. C. No. 39284. S. No. 46–619 M.)

QUANTITY: 43 *first aid kits* at Philadelphia, Pa.

SHIPPED: 5–11–56, from Bellbluff, Va., by Goldberg Army & Navy Goods.

ACCOMPANYING LABELING: Leaflet entitled "First Aid Instructions Vest, Emergency, Sustenance Type C–1."

RESULTS OF INVESTIGATION: Examination showed the product to be a 4'' x 3'' plastic case containing the following: 4 adhesive bandages, 1 vial of mild iodine, 2 compress bandages, 1 small cake of soap, 1 plastic vial of amphetamine sulfate tablets, 1 plastic vial of sulfadiazine tablets, 1 plastic vial of atabrine tablets, 1 plastic vial of halazone tablets, and 1 plastic vial of salt tablets.

LIBELED: 6–19–56, E. Dist. Pa.

CHARGE: 503 (b) (4)—the article contained amphetamine sulfate tablets, sulfadiazine tablets, and atabrine tablets, which were drugs subject to 503 (b) (1), and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8–1–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5307. Dexedrine Sulfate tablets, secobarbital sodium capsules, and capsules containing a mixture of secobarbital sodium and amobarbital sodium. (F. D. C. No. 39831. S. Nos. 46–264/5 M, 46–272/5 M.)

INDICTMENT RETURNED: 5–9–57, E. Dist. Pa., against Bernard Friedman, t/a Barclay Pharmacy, Philadelphia, Pa.

SHIPPED: Between 4–3–56 and 4–26–56, from Pennsylvania to New Jersey.

CHARGE: 502 (f) (1)—when shipped, the labeling of the articles failed to bear adequate directions for use.

PLEA: Nolo contendere.

DISPOSITION: 7–8–57 and 9–4–57. The defendant was fined $6,000, given a jail sentence of 6 months, which was suspended, and placed on probation for 1½ years.

5308. Vit-Ra-Tox No. 21 and No. 16. (F. D. C. No. 35574. S. Nos. 55–951/4 L, 62–612 L.)

INFORMATION FILED: 12–9–54, Dist. Mass., against V. E. Irons, Inc., Boston, Mass., and V. Earl Irons, president and treasurer.

SHIPPED: Between 12–3–52 and 7–28–53, from Massachusetts to Missouri and New York.

LABEL IN PART: (Ctn.) "Vit-Ra-Tox No. 21 A Natural Food with green life In three bottles Two of No. 21A and one of 21B"; (btl.) "V. E. VIT-RA-TOX Irons Inc. No. 21A . . . . . Part of No. 21 A Natural Food with green life Raw Veal Bone and Defatted Wheat Germ VIT-RA-TOX No. 21A with green life (2-⅛ oz.) Green Life is a concentrate of the juices of 2 or more young, tender green cereal (grain) shoots (oats, corn, barley, rye or wheat); raised in one of the richest soils known to man on the world's largest Organic Com-

*See also Nos. 5302–5304.

post Farm near Kansas City, Mo.; extracted in a manner as to retain Nature's vitamins, living enzymes, synergistes, and activating minerals (except Vitamin D); a rich natural source of Carotene (provitamin A) and the complete natural complexes of Vitamins B, C, E, F, and K with the P fractions of the C complex and the WULZEN factor of the F complex, plus the living enzymes, synergists and mineral activators. It contains organic iron, calcium, phosphorus, iodine and a host of other minerals in trace amounts with Live Chlorophyll in its natural, untreated, and edible state. * * * Contents 4-⅛ ozs. in tablet form 180 tablets of 10 grs. each"; (btl.) "No. 21B V. E. VIT-RA-TOX Irons Inc. Part of No. 21 A Natural Food This part containing: Garlic Derivative Wheat Germ and Lecithin as Emulsifiers Contents 60 capsules VIT-RA-TOX No. 21B Two green capsules contain the following: Garlic Derivative 4 mgs. Formulated in the following Organic Base (good natural sources of nutritional elements.) Wheat Germ Oil 129.6 Mgs. and Lecithin from soy beans 666.4 mgs. are used as emulsifiers"; (ctn.) "V. E. Vit-Ra-Tox Irons Inc. Products VIT-RA-TOX No. 21 A Dietary Supplement in tablet form containing a mixture of dried extracted juices of Cereal Grasses green life Plus Bone Meal Brewer's Yeast Fish Liver Oils Alfalfa Kelp (or Dulse)"; (btl.) "V. E. VIT-RA-TOX Irons '16' An Adsorbent Aid in Systemic Detoxification and An Intestinal Purificant National Distributors Irons & Moore Division of V. E. Irons, Inc., Boston, Mass. Contents One Quart 'Mechanically active adsorbent ingredient: Colloidal Bentonite (U. S. P. Grade) Distilled water as vehicle with certified flavor and color."

ACCOMPANYING LABELING: *Vit-Ra-Tox No. 21.* Leaflet headed "No. 21 A Natural Food * * * with green life the basis of all basic sources of Natural Vitamins"; leaflet entitled "What Price Refinement"; sales kit containing (a) looseleaf booklet known as "Civilization—Benefactor or Bandit," the first page of which begins "The National Malnutrition—D. T. Quigley"; (b) booklet entitled "Your Future with Irons and Moore"; (c) pamphlet entitled "Vitamins What Are They?" (d) pamphlet entitled "No. 21—A Natural Food Concentrate with green life," and pamphlet entitled "Ask for your Money Back Now"; and various issues of a newsletter.

Vit-Ra-Tox No. 16. Letter beginning with the words "Dear Friend"; pamphlet entitled "Ask For Your Money Back Now"; and certain portions of a sales kit, namely, (a) two pages of a looseleaf booklet known as "Civilization—Benefactor or Bandit," the first page beginning "Civilization? Primitives Can Teach Us Much" and the second page beginning "Civilization vs. Primitives Toxemia Eliminated the Primitive Way"; and (b) pages 14–18 of a booklet entitled "Your Future with Irons and Moore."

CHARGE: *Vit-Ra-Tox No. 21, No. 21A,* and *No. 21B.* 502 (a)—the labeling of the articles, when viewed in its entirety as well as through specific claims, contained false and misleading representations that nearly everyone in this country is suffering from malnutrition or in danger of such suffering because of the demineralization and depletion of soils and the refining and processing of foods; that practically all illnesses and diseases of mankind are due to improper nutrition; that the best way to treat, cure, and prevent all the diseases of mankind would be by using the articles; that the articles possessed nutritive properties superior to any other vitamin and mineral supplement; that the articles would be effective in the cure, treatment, and prevention of the ills and diseases of mankind, including heart trouble, diabetes, indigestion, anemia, nervousness, varicose veins, asthma, hay fever, tuberculosis, cancer, arthritis, polio, mental

disease, dental decay, high blood pressure, kidney disease and diseases of the digestive system, respiratory system, glands, bones, skin, and muscles; that the article designated No. 21B, by reason of its garlic content, possessed marvelous healing power and would be effective in the cure, treatment, and prevention of high blood pressure, low blood pressure, intestinal infections, polio, tuberculosis, arterial disease, flatulence, infections of the respiratory system, worms, lice and nits, skin disease and ulcers, symptoms of aging, and would make the dread symptoms of diphtheria present in the throat disappear; and that the action of the portion of the articles designated as No. 21B was, by reason of its garlic content, comparable to that of penicillin.

Vit-Ra-Tox No. 16. 502 (a)—the labeling of the article, when viewed in its entirety as well as through specific claims, contained false and misleading representations that the article was an adequate and effective treatment for rheumatic and pulmonary affections, disorders of the scrofulous and eczematous types, abscesses, cleansing of sores and wounds, serious disturbances of the digestive tract, and bacterial infections of the gut; and that the article was effective as a systemic detoxificant.

All articles. 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use for the diseases and conditions for which they were intended.

The information alleged also that a quantity of *Vit-Ra-Tox No. 21* consisting of *No. 21A* and *No. 21B* was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 9–18–56 and was concluded on 10–2–56, with the return by the jury of a verdict of guilty. On 10–22–56, the court imposed a fine of $6,000 against the corporation and sentenced the individual to 1 year in jail.

The case was appealed to the United States Court of Appeals for the First Circuit; and on 4–24–57, after consideration of the briefs and arguments of counsel, the court handed down the following opinion (244 F 2d 34):

MAGRUDER, *Chief Judge:* "V. E. Irons, Inc., and V. Earl Irons in his individual capacity stand convicted, after a three-weeks trial, on a six-count information for causing the introduction into interstate commerce of misbranded food and drugs in violation of the Federal Food, Drug, and Cosmetic Act,[1] 52 Stat. 1040, as amended, 21 U. S. C. § 301 *et seq.*

"Count I of the information charged that the defendants (appellants herein) caused to be introduced into interstate commerce articles of food, known as Vit-Ra-Tox 21A (raw veal bone, defatted wheat germ, and the concentrate of juices of young, green cereal shoots) and Vit-Ra-Tox 21B (garlic derivative, wheat germ, and lecithin as emulsifiers), which were misbranded under 21 U. S. C. § 343 (j)[2] in that they 'purported to be and [were] represented as a food for special dietary uses by man by reason of [their] vitamin and mineral content and [their] label[s] failed to bear such information concerning [their] vitamin and mineral properties as had been determined to be and by regulations[3] prescribed as necessary in order fully to inform purchasers as to [their] value for such uses'.

---

[1] Evidence introduced at the trial seems conclusively to establish that the defendants did introduce their products into interstate commerce. No issue as to this has been seriously pressed on appeal.

[2] § 343. Misbranded food.

A food shall be deemed to be misbranded—. . .

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

[3] The pertinent regulations are as follows:

§ 125.2 *General label statements.* (a) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented

(Footnote continued on p. 226)

"Count II charged that the appellants caused to be introduced into interstate commerce articles of drug known as Vit-Ra-Tox 21A and Vit-Ra-Tox 21B (the same products referred to in Count I) which were (a) misbranded under 21 U. S. C. § 352 (a)[4] in that their accompanying labeling—consisting of certain leaflets and various issues of a newsletter—falsely represented 'when viewed in [their] entirety as well as through specific claims . . . that nearly everyone in this country is suffering from malnutrition or in danger of such suffering because of demineralization and depletion of soils and the refining and processing of foods, that particularly all illnesses and diseases of mankind are due to improper nutrition, that said article[s] possessed nutritive properties superior to any other vitamin and mineral supplement, that said article[s] would be effective in the cure, treatment, and prevention of the ills and diseases of mankind,' including certain specific diseases; and which were (b) misbranded under 21 U. S. C. § 352 (f) (1)[5] in that their labeling failed to bear adequate directions for the use for which they were intended, namely, for treatment of the specific diseases which appellants represented that the drugs could cure or prevent.

"Counts III and V named two products similar to the vitamin and mineral products specified in Counts I and II, and alleged that the said articles (being also articles of 'drug' within the meaning of the statutory definition) were

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for any special dietary use by man, its label shall bear a statement of the dietary properties upon which such use is based in whole or in part. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any other dietary property of such food upon which such use is so based.

(b) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for special dietary use by reason of its use for treating any disease resulting from a dietary deficiency in man, its label shall bear, in addition to the information required under paragraph (a) of this section, adequate directions for such use.

§ 125.3 *Label statements relating to vitamins.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of:

Vitamin A or its precursors,
Vitamin B_1 (thiamine),
Vitamin C (ascorbic acid),
Vitamin D, or
Riboflavin (vitamin B_2, vitamin G).

the label . . . shall bear a statement of the proportion of the minimum daily requirement for such vitamin supplied by such food when consumed in a specified quantity during a period of one day. . . .

(2) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of any vitamin not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such vitamin in a specified quantity of such food. The quantity of food specified as required by this section, shall be the quantity customarily or usually consumed during a period of one day or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such vitamin has not been established, the label shall also bear the statement 'The need for _____ in human nutrition has not been established,' the blank to be filled in with the name of such vitamin. . . .

§ 125.4 *Label statements relating to minerals.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of:

Calcium,
Phosphorus,
Iron, or
Iodine,

the label . . . shall bear a statement of the proportion of the minimum daily requirement for such element supplied by such food when consumed in a specific quantity during a period of one day. . . .

(2) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such element in a specified quantity of such food. Except in the case of foods subject to § 125.9, the quantity of food specified as required in this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall also bear the statement 'The need for _____ in human nutrition has not been established,' the blank to be filled in with the name of such element. . . . (21 C. F. R. 247–49 (1955))

[4] § 352. Misbranded drugs and devices.
A drug or device shall be deemed to be misbranded—
(a) If its labeling is false or misleading in any particular.

[5] § 352. Misbranded drugs and devices.
A drug or device shall be deemed to be misbranded— . . .
(f) Unless its labeling bears (1) adequate directions for use . . .

introduced into interstate commerce on or about July 28, 1953, and July 14, 1953, respectively, consigned to the Delvita Company, Wilmington, Delaware, and to one Joseph T. Stoeckl, of Buffalo, New York, respectively, and were (a) misbranded under 21 U. S. C. § 352 (a) in that their labeling, when viewed in its entirety, falsely represented and suggested that 'nearly everyone in this country is suffering from malnutrition or is in danger of such suffering because of the demineralization and depletion of soils and the refining and processing of foods, that practically all human ailments and diseases are traceable to improper nutrition, that the best way to treat, cure, and prevent all the diseases of mankind would be by using said article[s] of drug, that said article[s] [possess] nutritive properties superior to any other vitamin or mineral supplement, that said article[s] constituted an adequate and effective cure, preventive and treatment' for various specific diseases; and were (b) misbranded under 21 U. S. C. § 352 (f) (1) in that their labeling failed to bear adequate directions for use.

"Counts IV and VI involved a different product, known as Vit-Ra-Tox '16,' whose label described it as 'An Adsorbent Aid in Systematic Detoxification and An Intestinal Purificant,' and alleges that said article of drug was introduced into interstate commerce on or about July 28, 1953, and December 3, 1952, respectively, and consigned to the Delvita Company, Wilmington, Delaware, and to one Joseph T. Stoeckl, of Buffalo, New York, respectively, and was (a) misbranded under 21 U. S. C. § 352 (a) in that its labeling falsely represented that the article was an adequate and effective treatment for certain specific disorders and disturbances; and was (b) misbranded under 21 U. S. C. § 352 (f) (1) in that its labeling failed to bear adequate directions for use.

"At the trial it was shown that appellants were engaged in the manufacture and distribution of certain 'natural' vitamin products (distinguished from sythetic vitamins in that they are produced from natural food sources), and that sales of the products were made to consumers by distributors who received from appellants both the product to be sold and supporting literature. The evidence indicated that appellants recruited salespeople from among their customers and acquaintances, as well as through advertisements in newspapers. Selling techniques were explained to these people at meetings and by printed material comprising the sales kit, which contained certain leaflets in addition to supplemental newsletters written at frequent intervals by appellants and sent to such distributors. The printed promotional material was shown to be an integral part of the selling process, and constitutes the major source of the government's proof of the charges contained in the information.

"The written, printed, and graphic material used was all identified and introduced into evidence by a food and drug inspector of the Department of Health, Education, and Welfare, who had posed as a salesman in order to obtain the material from appellants. The inspector made application and became an accepted distributor; he obtained a complete sales kit, purchased products, attended a lecture by Irons, and received a series of newsletters.

"At the conclusion of the trial the jury returned a verdict of guilty against both defendants on all six counts. The court sentenced V. Earl Irons to one year of imprisonment on each of the six counts, the sentences to run concurrently; and imposed upon the defendant corporation a fine of $1,000 on each count. Appeals were duly taken by both defendants.

"The brief for appellants lists twelve major points as grounds for reversal, as well as a large number of subpoints. But after a complete reading of the voluminous record, we are satisfied that no error was committed by the district court.

"Since appellants make no serious argument with respect to Count I, it may be dealt with summarily. The label on the carton introduced into evidence by the government states that Vit-Ra-Tox No. 21A retains 'Natures' vitamins, living enzymes, synergists, and activating materials (except Vitamin D); a rich natural source of Carotene (provitamin A) and the complete natural complexes of Vitamins B, C, E, F, and K with the P fractions of the C complex and the Wulzen factor of the F complex, plus the living enzymes, synergists and mineral activators. It contains organic iron, calcium, phosphorus, iodine and a host of other minerals in trace amounts . . . .' The label thus represents that the product has special dietary uses for man, by reason of its vitamin and mineral properties, within the scope of the Administrator's regulations con-

tained in note 3, *supra;* and because there is no claim that the label satisfied the requirements of the regulations, it is quite clear that there was a violation of the Act, so far as Count I is concerned.

"Before proceeding further, it is to be noted that the Act makes a distinction between the terms 'label' and 'labeling'. Under 21 U. S. C. § 321 (k), 'label' is defined to mean 'a display of written, printed or graphic matter upon the immediate container of any article . . . .' But by 21 U. S. C. § 321 (m), 'labeling' means 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' It is clear that the term 'labeling' must be given a broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article. 'One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.' *Kordel* v. *United States*, 335 U. S. 345, 350 (1948). There is no doubt that the printed circulars, pamphlets, brochures and newsletters distributed by appellants in the present case constituted 'labeling' within the statutory definition, and thus may properly be received in evidence as proof of false or misleading statements.

"In determining whether such labeling contained 'false or misleading' statements, we must be careful not to read the literature with the eyes either of experts in nutrition or of overly skeptical buyers. What is pertinent is the effect the claims would have on those to whom they are addressed, namely, prospective purchasers and actual customers of appellants, who cannot be presumed to have special expertness or to be unduly cautious, but who are more likely than not to be persons who are pathetically eager to find some simple cure-all for the diseases with which they are afflicted or who are susceptible to luridly painted scare literature as to the prospect of being disease-ridden unless they consistently partake of the vaunted drug product. This approach has been authoritatively approved. In *Federal Trade Commission* v. *Standard Education Society*, 302 U. S. 112, 116 (1937), it is stated: 'The fact that a false statement may be obviously false to those who are trained and experienced does not change its character, nor take away its power to deceive others less experienced. There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. The best element of business has long since decided that honesty should govern competitive enterprises, and that the rule of *caveat emptor* should not be relied upon to reward fraud and deception.' See also *Donaldson* v. *Read Magazine, Inc.*, 333 U. S. 178, 188 (1948).

"When appellants' labeling is examined in this light and in its entirety, it readily appears that the government introduced at least sufficient evidence to warrant submission to the jury of the issues whether appellants made the representations charged against them, and whether these representations were false or misleading.

"The literature contains considerable material that is either obviously harmless or irrelevant to this case, such as lists of food with their vitamin content, instructions to salesmen, and shipping details for the various products. But, beyond that, many representations are made that, fairly interpreted, provide adequate support for the government's charges. There are, first of all, numerous assertions that 'all human ailments' can be traced to nutritive deficiencies and that various specific ills are caused thereby. For example, there is the statement:

> The evidence is overwhelming! That we Are what we Eat. That practically All Human ailments are traceable to our food. From the time we are conceived until we reach 150 lbs;
>
> It's The Material Out of Which we are built that determines the structure. If that material is faulty the structure Breaks Down. If it is Not faulty, it does Not Break Down . . . It's our Food, that makes us sick or well.

Similarly, in one of appellants' pamphlets it is stated: "We believe that practically all the ailments that beset our civilized world are caused by deficient foods which can lower one's resistance."

"With respect to specific diseases, the literature quotes from the writings of one Dr. Sutherland [6] that:

> At the present time many conditions are considered as essentially deficiency diseases and are associated in one's thought with the classical Beri-Beri, Pellagra, Rickets and Scurvy. Such conditions are Infantile Scorbutus, Marasmus, Dentition Difficulties and Imperfect Teeth in Children and Adults, Dyspepsias, Indigestions, Diarrhoeas and Constipation, Obesity, Inability to Nurse Children, Diabetes, Neuroses, Infantile Paralysis, Certain Myalgias or "Rheumatism," Dementia Praecox, and even Tuberculosis and Cancer. The list can be extended but it is already a formidable one.

"Furthermore, there are numerous examples in the record of statements attributing extraordinary powers to appellants' products:

> Our customers are indeed fortunate that Vit-Ra-Tox was chosen by Green Life Products Co. of Kansas City, as the First and Only organization of its Kind to offer to the public Green Life, the richest, most potent and easily assimilated Natural Food, known to man.
>
> We believe that Green Life, because of its high concentration of Nature's unknown mysteries, is at present the only hope for overcoming the deficiencies of civilized, processed foods. Green Life alone should be able to help lessen current deficiencies in an average reasonable daily diet if the right amount for each individual can be determined through experience.

"At another point appellants modestly state in an unqualified way that 'It [Vit-Ra-Tox No. 21] is the One Hope for suffering humanity.' And again, that ' "This Product" *alone* of all products now on the market has *all* the vitamins, minerals, enzymes, co-enzymes, mineral activators and synergists (co-workers or helpers) needed by the human body (except Vitamin D).'

"Apart from these general representations about the value of their product, the record discloses that appellants claimed the power to cure or ameliorate specific diseases. These claims are to be found both with respect to the products which were the subject of Counts II, III and V, and also with respect to those which were the subject of Counts IV and VI. Regarding the products mentioned in Counts II, III and V, it is said: 'Hence Dr. Lee believes that arthritis cannot possibly reside permanently in a *body* which has a sufficient daily intake of this product.' And, again quoting Dr. Lee,[7] 'No one could continue to have arthritis and use this product daily.'

"With respect to Vit-Ra-Tox 16 (the Bentonite product) referred to in Counts IV and VI, a book of appellants' which was provided to all distributors quoted, somewhat out of context, from U. S. Government Bureau of Mines Booklet No. 609: 'Moistened with water or glycerin, it ["Alkali Bentonites"] also has been used, apparently with some success, for rheumatic and pulmonary affections, disorders of the scrofulous and eczeatous type, abscesses, and the cleansing of sores and wounds.'

"Laying aside these specific claims, it is true that most of the representations in the literature relating to diseases are more indirect; virtues of appellants' products are juxtaposed with descriptions of the symptoms or cures for various diseases, although no statement is made overtly correlating the products with the diseases. For example, the first few pages of one of the pamphlets are devoted to very general statements about nutritive deficiencies in the United States; it then goes on to say:

> No one can listen to the radio or television day after day without being reminded of the enormity of this health problem. Constantly we hear

[6] The literature employs quotations from the writings of others. It is obvious that so long as these writings are quoted with approval, they become the representations of appellants and can be used by the government to sustain its charges.

[7] The newsletter containing the second statement attributed to Dr. Lee said: "The above is what Dr. Lee thinks of the base of our new product and we consider him tops, the best authority on vitamins and minerals in the country today." Dr. Lee testified at the trial. It appeared that he was a licensed dentist (1924) not presently practicing dentistry but whose "principal business" was the Lee Engineering Company which manufactured custom-made electrical equipment.

There was evidence that these representations were effective to induce purchases of "Green Life". One witness testified that he was told, when handed the literature, that the product would cure arthritis and that he bought it for that purpose.

appeals for donations to the Heart Fund on the grounds that over 50% of all the deaths in 1951 were due to Heart trouble of some kind. Yet in 1890 only 5% of the deaths were from Heart Disease. This indicates a 1,000% increase in 60 years. Can anyone doubt that this is a major problem?

In their recent plea, the Cancer Fund announced that one-fifth of those now living will die of Cancer (⅕ of 150,000,000 is 30,000,000). Since 1890 the percent of Deaths from Cancer has increased 650%. In the drive for a better understanding of Diabetes it was broadcast and advertised that 1,000,000 people in the country have Diabetes that don't know they have it. Dr. Joslin, the greatest living authority on Diabetes states that at the rate we are going, almost everyone in America will have Diabetes within 50 years.

"Later on in the same pamphlet appellants proceed to discuss the virtues of their products: 'To the best of our knowledge there is absolutely nothing on the market today with which Vit-Ra-Tox #16 can be compared. It seems to have the faculty of assisting the body in removing toxins and poisons.' Another example of the juxtaposition of a discussion of appellants' products with a discussion of specific diseases is contained in one of the newsletters in which, under the heading 'The Garlic Cure for Tuberculosis', there is a long exposition of certain alleged cures of tuberculosis by garlic and garlic products. The latter part of the newsletter contains information for salesmen as to how to speed up their orders for the Vit-Ra-Tox products which contain a garlic derivative. The record discloses many other illustrations of references to specific diseases cleverly coupled with boosts for or information concerning Vit-Ra-Tox. On the basis of this record it is not at all surprising that a lay jury reading the literature came to the conclusion that special curative or at least preventive powers for the diseases mentioned were claimed by appellants for their Vit-Ra-Tox line.[8] And if such was the impression made upon the jury, it seems more than likely that a prospective purchaser, hoping finally to obtain relief from a long-endured disease, would not read appellants' literature with any skeptical literalness. Bearing in mind the broadly remedial purposes of the Act in preventing deception, the Congress must be taken to have meant to strike not only at palpably false claims but also at clever indirection and ambiguity in the creation of misleading impressions. See *United States* v. *One Device, Intended for Use as a Colonic Irrigator*, 160 F. 2d 194, 200 (C. A. 10th, 1947).

"In order to show that many of the representations contained in the literature, or labeling, were 'false or misleading', the government put on the stand five expert medical witnesses, authorities in the field of nutrition or internal medicine.

"These experts testified, first of all, that not all human illnesses are traceable to nutritive deficiencies, as appellants claimed, pointing out that some diseases are caused by congenital defects, others by specific viruses or bacteria, and that numerous degenerative diseases of old age have nothing to do with nutrition. Moreover, they stated that, after experiments with appellants' products, these were found to lack the powers attributed to them, either as general aids to health or in connection with the specific diseases mentioned in the literature. One doctor said: 'In the directions recommended, it would have absolutely no effect in any of the ten leading causes of death in the United States, or in any other way you would like to take it.' There is no need to recite the evidence in detail, for the record is replete with medical testimony

[8] On its cartons and in one or two of appellants' newsletters or pamphlets, one may find disclaimers such as the following:

"Important—We do not diagnose or prescribe

"Neither we nor our Vit-Ra-Tox Distributors are doctors. We do not attempt to diagnose or prescribe. We do not approach our customer's health problem from the standpoint of specific ailments. We are however, interested in teaching them how, to the extent possible through nutritional influences, we can help them. . . .

"Our sales talk and theory of body building through nutritional elements are not to be interpreted as entering the field of medicine or as violating a doctor's prerogative. Since, therefore, we try only to improve the nutritional vitality of our customers, if any dangerous acute conditions exist or are suspected, a physician should be consulted."

Such disclaimers occur only rarely. And even when they appear in conjunction with some of the literature found to be false or misleading, they should not be regarded as conferring any immunity on appellants, so long as the literature in its entirety is reasonably understood by readers to make the curative claims alleged by the government.

contradicting the various claims; and there is no doubt that the jury was provided with a sufficient foundation for its findings.

"Appellants introduced their own expert witnesses at the trial, but it does not take one well versed in the field of nutrition to appreciate why the jury might have accorded their testimony diminished weight. One of them was a soils expert who was not shown to be qualified to discuss human nutrition or the claim that soil deficiency resulted either in national malnutrition or in diseases of man. Several practising physicians also testified, but none seemed to possess extensive qualifications in nutrition. One of these, who had not practised medicine for over thirty years, testified to laboratory tests he made for high blood pressure using garlic on cats and on humans, but he admitted on cross-examination that, to supply a daily dose comparable to the dose of garlic administered in his tests, he would have to give a patient 855 tablets of Vit-Ra-Tox 21B per day. Appellants also presented two dentists, neither of whom disclosed any additional training to equip them as an expert in nutrition, and one of whose writings—those of Dr. Lee—had been employed as part of appellants' sales literature. See note 7, *supra*. Incidentally, this is the Dr. Lee whom one of the government's experts caustically referred to as 'known as one of the biggest charlatans in the food quackery business.' The jury, after hearing these expert witnesses for both sides, was in a position to compare their respective qualifications, and we are not prepared to set aside its determination as to where the truth lay.

"Concerning the accuracy of therapeutic claims, it was held in an earlier mail fraud case that fraud could not be found to exist so long as bona fide differences of medical opinion existed. *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94 (1902). But the terms of the Federal Food, Drug, and Cosmetic Act of 1938, outlawing 'false or misleading' labeling, and the regulations issued under the Act, proceed upon a different basis. One may be guilty of the misdemeanor described in 21 U. S. C. § 333 (a) without having any intent to defraud or mislead. In contrast with this is the provision of § 333 (b), which imposes more severe penalties in case of a violation of any of the provisions of § 331, 'with intent to defraud or mislead'. In the applicable regulations it is provided: 'The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.' 21 C. F. R. § 1.3. The cases decided under the Act indicate that the jury will be allowed to determine the truth of a therapeutic claim as it would that of any other fact. *United States* v. *Kaadt*, 171 F. 2d 600, 603 (C. A. 7th, 1949). The danger has been pointed out, in 67 Harv. L. Rev. 632 at 654, 'that juries, if always allowed to determine the validity of a claim after hearing contradictory medical testimony, will brand false new, temporarily unpopular, but possibly correct scientific theories.' On the other hand, the potentiality of harm to gullible consumers, from acceptance of false or misleading representations, may be just as real even though the maker of the representations has a bona fide belief in their truth. Which of these more or less competing considerations is to be accorded priority is, of course, a matter of policy for the Congress to decide. See *United States* v. *Dotterweich*, 320 U. S. 277, 284–85 (1943).

"It must be remembered that a representation may be 'misleading' from the very fact of overemphasis and exaggeration, even though the product in question may be helpful, and in some circumstances useful, though not really indispensable to good health. This is no doubt what one of the government's expert witnesses had in mind when he testified:

> Well, obviously food is important, and we have to develop our bodies from building materials and blocks we get from food; but in order to utilize our food properly we have to have a liver that is functioning, and a pancreas that is functioning, and various other of our body organs, in order to utilize food properly. So we may very well get the best of food, and yet if we have faulty processes of digestion, or liver functioning, which is mentioned specifically, we can't get the most out of our food. On the other hand, if we have a good liver and a good pancreas and a good insides, you might say, working properly and we get poor food, we aren't going to do

a good job either, so the answer to the last part is Yes or No, food is important but other things are also important.

"The same expert testified subsequently, on cross-examination:

> If anybody eats nothing but sugar, that is, this white sugar you mentioned nothing but white bread, you would need some type of vitamin and mineral supplement. If you put in a little milk, if you put in a little meat, if you put in a little egg, vegetable, fruits, you don't need Mr. Irons or anybody else, if you are in good health.

"Turning now to the second charge contained in each of Counts II–VI of the information, that is, that the articles of drug were misbranded in that their labeling failed to bear 'adequate directions for use' for the various diseases and conditions for which they were intended, it may be pointed out that we are free to look to all relevant sources in order to ascertain what is the 'intended use' of a drug, and are not merely confined to the labels on the drug or the 'labeling'. The legislative history of the 1938 Act makes this clear. See Dunn, Federal Food, Drug, and Cosmetic Act 111–12, 240 (1938). Such also has been the undeviating opinion of the courts which have had occasion to deal with the issue. For example, in a recent decision the Third Circuit said:

> The intended uses of the products in the present issue as in *Kordel* [*Kordel* v. *United States*, *supra*, 335 U. S. 345] were to cure, ameliorate or prevent diseases. The evidence to prove their uses included both graphic materials distributed and testimony of oral representations to users and prospective users. The latter are no less relevant on the question than the former. Both show that the products shipped were to be used as drugs. "*United States* v. *El Rancho Adolphus Products et al.*, F. 2d (C. A. 3d Jan. 29, 1957). See also *United States* v. *3 Cartons, More or Less, No. 26 Formula GM etc.*," 132 F. Supp. 569, 574 (S. D. Cal. 1952).

"In the present case, therefore, we are entitled to utilize all of appellants' literature as well as the oral representations made by V. Earl Irons at his lectures or by authorized sales distributors.[9]

"As a matter of fact, appellants introduced no label which provided adequate directions if the use of the products is to be taken to effect the cure or prevention of the various diseases mentioned in the literature. Indeed, appellants do not maintain that they ever issued any such label, but content themselves in saying that the government's case must fall because there was no showing that the voluminous literature admitted in evidence constituted *all* of the labeling of the products; in other words, it is argued that other items of labeling which might exist might have contained adequate directions for use. But once the government has introduced into evidence a substantial

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[9] The following testimony of the food and drug inspector about a speech made by appellant V. Earl Irons was thus admissible in order to show the intended use of the products.

"Q. In what way? What did he say about conditions?

A. Well, he mentioned there are four different types of cancer, he mentioned female troubles, and he also mentioned sexual impotence, sexual perversion. With regard to female troubles, he said, he mentioned a case of a woman who had not menstruated for a long time and after starting on Vit-Ra-Tox had no more trouble in that regard.

Mr. Foley: If your Honor please, I just want to make sure I have a running objection to all of this.

The Court: Oh, yes, yes. Perfectly admissible.

Q. Will you go on mentioning the others?

The Court: Go ahead.

A. Certainly.

Q. Give to the best of your memory the substance of this lecture given by Mr. Irons. A. When he began to talk about cancer, he made the statement: 'Ladies and gentlemen, I would rather have cancer than a bad case of asthma because cancer can be cured in three to ten weeks.'"

One consumer testified without objection that he had bought some Vit-Ra-Tox No. 21 upon an oral representation by the salesman that it would cure arthritis (see note 7, *supra*). The court charged the jury, in terms that were not objected to at the conclusion of the charge (see Rule 30 F. R. Cr. P.), that they might consider oral statements of Irons or a distributor of the corporation in determining whether the product was offered for treatment of specific diseases.

number of documents constituting 'labeling' of the various drug products, none of which provided 'adequate directions for use', it seems perfectly reasonable to require that the defendants have the burden of going forward with the production of other labeling which does satisfy the demands of the statute. It would be quite unthinkable to impose upon the government the further necessity of proving that there are no other, secreted, labelings in existence, especially since all such literature used by appellants can be assumed to be in their possession. Therefore we find no error in the conclusion that the labeling of appellants' products did not provide adequate directions for use.

"Appellants present a variety of other defenses, some of which are clearly untenable. For example, it is a bit late in the day to sustain the assertion that the Federal Food, Drug and Cosmetic Act is unconstitutionally vague. Nor, after a review of the entire record, are we able to agree that the court below committed prejudicial procedural errors in its conduct of the trial.

"However, the propriety of the sentences imposed merits a brief comment. It is argued that Counts I and II of the information and Counts III and IV each charged but a single offense and therefore that it was an error to sentence appellants separately on each of these four counts. (The individual defendant is hardly in a position to raise this point, since the sentences imposed upon him were to run concurrently. However, separate fines were imposed upon the corporate defendant as to each count.) The rule is now well settled that a conviction with sentence upon one indictment or information does not bar conviction with sentence upon another 'if the evidence required to support the one would not have been sufficient to warrant the conviction upon the other without proof of an additional fact . . . .' *Eberling* v. *Morgan*, 237 U. S. 625, 631 (1915); *Ekberg* v. *United States*, 167 F. 2d 380, 384 (C. A. 1st, 1948). In the present case this test is satisfactorily met. The violation in Count I is based upon the charge that the article was represented as a food for special dietary uses by reason of its vitamin and mineral content, and that the label did not bear certain information required under the authorized regulations issued by the Secretary of Health, Education, and Welfare. In contrast, Count II alleges the same product to be a misbranded drug on the basis of false and misleading statements which appear on the 'labeling' literature disseminated by appellants; and to obtain a conviction under this count the government had to prove the additional fact that the statements contained in such literature were false or misleading.

"The arguments based on Counts III and IV are even more flimsy, for these counts involve entirely different drugs. The drug named in Count III is a tablet known as Vit-Ra-Tox No. 21, which is said on its label to contain 'a mixture of dried extracted juices of cereal grasses green life, plus bone meal, brewer's yeast, fish liver oils, alfalfa kelp (or dulse).' The drug which is the subject of Count IV is a liquid known as Vit-Ra-Tox No. 16, described in the label thus: 'Colloidal Bentonite (U. S. P. Grade). Distilled water as vehicle with certified flavor and color'. Obviously they are different drugs. As the statute forbids the introduction into interstate commerce of *any* drug that is adulterated or misbranded (21 U. S. C. § 331 (a)), Counts III and IV do not charge the commission of a single offense but rather two separate and distinct offenses, and the sentence imposed upon the corporate defendant by the trial court was therefore entirely proper."

A petition for a writ of certiorari was filed with the United States Supreme Court on 5–23–57, and on 6–17–57 the petition was denied.

5309. Nutrilite food supplement. (F. D. C. No. 39368. S. Nos. 20–490 M, 20–495 M.)

INFORMATION FILED: 2–7–57, Dist. Columbia, against Berneice Small, Washington, D. C.

ALLEGED VIOLATION: On 1–18–56 and 1–27–56, the defendant sold and delivered quantities of the article which had been orally recommended by the defendant for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded while held for sale.

LABEL IN PART: (Pkg.) "Nutrilite XX [or "X"] Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, diabetes, cancer, multiple sclerosis, malignancy, hardening of the arteries, low blood pressure, arthritis, Parkinson's disease, anemia, ulcers, eczema, and cataracts.

PLEA: Guilty.

DISPOSITION: 5–2–57. Suspended sentence of $100 fine or 30 days.

5310. **Nutrilite food supplement.** (F. D. C. No. 40145. S. No. 33–807 M.)

INFORMATION FILED: 8–22–57, W. Dist. Mo., against Floyd W. Raulie, Kansas City, Mo.

ALLEGED VIOLATION: On 11–12–56, the defendant, in the course of a sales talk, made oral representations that the article was an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the article being misbranded while held for sale.

LABEL IN PART: (Pkg.) "Nutrilite Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, colds, ulcers, arthritis, rheumatism, migraine headaches, high blood pressure, and Buerger's disease.

PLEA: Guilty.

DISPOSITION: 11–1–57. $25 fine.

5311. **Vitamin and mineral preparations.** (F. D. C. No. 39169. S. No. 42–544 M.)

QUANTITY: 1 drum containing 49,750 tablets at Laramie, Wyo.

SHIPPED: 6–18–56, from San Martin, Calif., by A. O. Zink.

LABEL IN PART: "Therapeutic Nutritional Mineral and Vitamins * * * Material Supplied By A O. Zink * * * Control #402555."

LIBELED: 8–8–56, Dist. Wyo.

CHARGE: 502 (f) (1)—when shipped, the article was represented for therapeutic use, and its label failed to bear adequate directions for that use.

DISPOSITION: 10–9–57. Default—destruction.

5312. **Home vibrator, wheat germ oil, Ver-A-Loe ointment, Papaya Rica, and Kuba Kup.** (F. D. C. No. 39845. S. Nos. 21–218 M, 57–974/7 M, 57–979 M.)

INFORMATION FILED: 7–23–57, W. Dist. Mo., against Lloyd C. Shanklin, t/a Harmony Health Foods & Juices, Kansas City, Mo.

ALLEGED VIOLATION: Between 8–20–56 and 8–22–56, the defendant made oral representations regarding the purposes, conditions, and diseases for which the articles were intended and caused a book entitled "Chemical Types of People and Their Foods" to accompany the *Ver-A-Loe ointment*, *Papaya Rica*, and *Kuba Kup* as labeling, which acts resulted in the articles being misbranded while held for sale.

LABEL IN PART: "Model E Home Vibrator," "Wheat Germ Oil Hormones As found in Wheat," "Ver-A-Loe Ointment * * * Contains Aloe-plant substance * * * in a Petrolatum base," "Papaya Rica Made from fresh papayas * * * Contains the pulp and juice, inverted papaya syrup, honey, citric acid, lemon juice and natural flavor," and "Kuba Kup * * * Contents Papaya Juice Pineapple Juice Sugar and Lime Juice."

CHARGE: 502 (a)—the above-mentioned book accompanying the *Ver-A-Loe ointment*, *Papaya Rica*, and *Kuba Kup*, while such articles were held for sale, contained false and misleading representations that the *Ver-A-Loe ointment* was an adequate and effective treatment for stomach disorders, indigestion, gastritis, ulcers, piles and hemorrhoids, fistulas, tumors, cancer, kidney troubles, cataract, arthritis, external ulcers, stomach ulcers, colitis, diabetes, burns, bruises, sprains, boils, swelling of the joints, eczema, and athlete's foot, and that the *Papaya Rica* and *Kuba Kup* were adequate and effective treatments for stomach disorders, indigestion, gastritis, ulcers, kidney troubles, stomach ulcers, colitis, and eczema.

502 (f) (1)—the labeling of all of the articles failed to bear adequate directions for use for the purposes, conditions, and diseases for which they were intended, namely, (home vibrator) heart trouble, rheumatism, neuritis, constipation, arthritis, gallstones, gallbladder trouble, spleen and pancreas trouble, kidney trouble, headaches, and sinus trouble; (wheat germ oil) heart trouble and improving the functions of the male and female regenerative organs and glands; (Ver-A-Loe ointment) bursitis, hemorrhoids, heart conditions, and burns; (Papaya Rica) bursitis, headache, toothache, diabetes, and to build up the heart; and (Kuba Kup) bursitis and to build up the heart.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 10–8–57, and was concluded on the same day, with the return by the jury of a verdict of guilty.

On 10–11–57, the court sentenced the defendant to serve 1 year in jail and placed him on probation for 2 years, which was to begin at the end of the imprisonment.

5313. Micro-Dynameter device. (F. D. C. No. 36854. S. No. 87–417 L.)

QUANTITY: 1 device at Mount Vernon, Wash.

SHIPPED: 2–21–52, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "Model SA–1 Micro-Dynameter."

ACCOMPANYING LABELING: Bulletins and pamphlets entitled "Supplement to Micro-Dynameter Handbook Drugs," "Bulletin T–2 Operating Instructions Model "S" Micro-Dynameter," "New Science in Body Analysis The Micro-Dynameter," "Supplement Micro-Dynamics * * * Opinions . . . Statements . . . Clinical Notes * * * The main object," "Bulletin of the Micro-Dynameter * * * New Device Detects Hidden Disease," "Bulletin of Micro-Dynameter Research Association Devoted to Scientific Body Analysis No. 2–S," "Bulletin of Micro-Dynameter Research Association Devoted to Scientific Body Analysis No. 8, September 1946," "Bulletin of Micro-Dynameter Research Association For Improving Clinical Results No. 1 * * * June 1951," "Bulletin of Micro-Dynameter Research Association For Improving Clinical Results No. 7," "Bulletin of Ellis Research Laboratories, Inc. The Micro-Dynameter No. M–3 September 1946," "Bulletin of Ellis Research Laboratories, Inc. The Micro-Dynameter No. 11 September 1950," "Bulletin of Ellis Research Lab-

oratories, Inc. The Micro-Dynameter No. M–2 Re-issue Jan., 1951," "Journal of Micro-Dynameter Research No. J–3," "Journal of Micro-Dynameter Research No. J–4," "Journal of Micro-Dynameter Research No. J–5," "Journal of Micro-Dynameter Research No. J–6," "Journal of Micro-Dynameter Research No. J–7," "Book Review Number Micro-Dynameter News Vol. 1 Chicago July 1946 No. 1," "Supplement Micro-Dynamics * * * 1935 * * * Clinical Notes . . . Statements . . . Opinions * * * Results Count," and "Bulletin T–3 Operating Instructions Model "SA–1" Micro-Dynameter"

RESULTS OF INVESTIGATION: The device appeared to be essentially a galvanometer for measuring electrical currents and electrical potentials of small magnitude.

LIBELED: 6–29–54, W. Dist. Wash., libel amended 10–17–55.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that the device was effective for diagnosing acidosis, alkalosis, anemia, angina pectoris, arthritis, asthma, brain injury, brain tumor, cancer, cerebral palsy, cholecystitis, chronic bronchitis, colitis, convulsions, cystitis, diabetes, epilepsy, gallbladder, gallstones, gingivitis, hay fever, heart disease, hernia, hypertension, hypotension, impinged nerves, infantile paralysis, influenza, insanity, intestinal "flu," kidney disorders, leukemia, migraine headaches, neuritis, pyorrhea, rheumatism, sciatica, strep. infection, stomach ulcers, thyroid condition, tuberculosis, and uremia; that the device was effective for treating asthma, blindness, cancer, uterine hemorrhage, palpitation of the heart, anemia, diabetes, dyspnea, hypertension, impaired vision, paralysis, polyarthritis, sarcoma of the uterus, strep. infection, tuberculosis, and uric acidosis; that the *Micro-Dynameter device* would measure the results of treatment, show what is actually going on deep down in the tissues of the body, was an aid to more accurate disease analysis, was a precision instrument for new clinical measurements, would measure nerve and tissue changes, and would give readings over a diseased area proportional to the extent of the disease, and thus disease could be mathematically diagnosed; that the *Micro-Dynameter device* would locate within the human body the cause of disease, help point to the correct differential diagnosis, provide the ability to make an accurate prognosis, provide the practitioner with the ability to restore at least 90 percent of previously unhelped cases to health by following its indications, tell patients how sick they really were and whether they could get well, give instantaneously the state of health or disease within the body, and determine the patient's recuperative ability; and that the device was the most scientific analytical instrument, would locate the exact origin or focus of disorder via an electrical method which was ultramodern and 100 percent accurate, and was the greatest step forward toward getting sick people well since December 18, 1895; and 502 (f) (1)—the labeling of the device failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: Ellis Research Laboratories, Inc., intervened in the case and filed an answer denying that the device was misbranded. Thereafter, upon motion of the parties, the United State District Court for the Western District of Washington entered an order on 3–15–55, removing the case for trial to the United States District Court for the Northern District of Indiana. Interrogatories were served upon the intervenor, and after objection to certain interrogatories had been sustained, answers to the remaining interrogatories were filed.

On 11–5–56, upon the consent of the parties that a condemnation decree might be entered without any adjudication as to any issue of fact or law, judgment of condemnation was entered and the court ordered that the device and accompanying labeling be turned over to the Department of Health, Education, and Welfare.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5314. Elixir Sonidel, triple sulfa suspension, and elixir butabarbital sodium. (F. D. C. No. 39844. S. Nos. 30–398 M, 43–265 M, 43–305 M.)

INFORMATION FILED: 7–24–57, E. Dist. Mo., against Halitosine Co., t/a Allan & Co., St. Louis, Mo.

SHIPPED: Between 1–30–56 and 10–30–56, from Missouri to Tennessee.

LABEL IN PART: (Btl.) "One Pint Elixir Sonidel [or "Contents I Pint Triple Sulfa Suspension" or "One Gallon Elixir Butabarbital Sodium"] * * * Allan & Co., St. Louis, Mo."

CHARGE: *Elixir Sonidel.* 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess since the article contained more phenobarbital than declared on its label; and 502 (a)—the label statement "Each 5 cc contains: Phenobarbital * * * 16.20 mg." was false and misleading.

Triple sulfa suspension. 501 (b)—the article, when shipped, purported to be a drug, the name of which "sulfacetamide, sulfadiazine, and sulfamerazine suspension" is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less than 90 percent of the labeled amounts of sulfacetamide, sulfadiazine, and sulfamerazine, the minimum permitted by the standard; and 502 (a)—the label statement "Each 5 cc Contains: Sulfadiazine .167 gms. Sulfamerazine .167 gms. Sulfacetamide .167 gms." was false and misleading.

Elixir butabarbital sodium. 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess since the article contained more butabarbital sodium than declared on its label; and 502 (a)—the label statement "Each 30 cc Contains * * * 0.2 gms. Sodium Butabarbital" was false and misleading.

PLEA: Guilty.

DISPOSITION: 9–20–57. $150 fine.

5315. First aid kits containing halazone tablets. (F. D. C. No. 39426. S. No. 51–900 M.)

QUANTITY: 818 *first aid kits*, each containing 1 bottle of *halazone tablets* at Denver, Colo.

SHIPPED: Between 1–26–56 and 5–10–56, from Tulsa, Okla.

LABEL IN PART: (Btl.) "100 Water Purification Tablets For Purifying Drinking Water In Canteens Halazone N. N. R. (P-sulfonedichloramidobenzoic acid) Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 75 percent to 98 percent of the declared amount of halazone. The National

*See also Nos. 5301, 5320 (veterinary preparation).

Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 8–23–56, Dist. Colo.

CHARGE: 501 (b)—while held for sale, the tablets purported to be and were represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and their strength differed from the official standard.

DISPOSITION: 2–8–57. Consent—claimed by Associated Traders, Inc., Denver, Colo. The bottles of *halazone tablets* were removed from the *first aid kits* and were destroyed.

5316. **Clinical thermometers.** (F. D. C. No. 39280. S. Nos. 51–556/7 M.)

QUANTITY: 1,469 *oral thermometers* and 358 *rectal thermometers* at Denver, Colo.

SHIPPED: Between 2–27–56 and 4–23–56, from Bronx, N. Y., by Dependable Thermometer Co.

LABEL IN PART: (Envelope) "Tested Clinical Thermometer Oral [or "Rectal"] Centigrade."

ACCOMPANYING LABELING: Leaflets designated "Certificate of Examination Fever Thermometer."

RESULTS OF INVESTIGATION: Examination revealed that 7 out of 24 oral thermometers and 3 out of 24 rectal thermometers failed to meet the labeled standard of accuracy and were not suitable for use as clinical thermometers because of faulty construction in that the gradation range was inadequate; there were too wide spaces between gradations; some had more than 5° C. per inch of scale; and some failed to retain pigment in markings when tested by recognized procedures.

LIBELED: 6–21–56, Dist. Colo.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the following statements in the labeling were false and misleading: "Tested" and "This Certifies that this registering clinical thermometer has been tested on the above date at 98°, 102°, and 106° F. or its equivalent in centigrade scale, and is correct within plus or minus .20° F. or .11° C. at any of these test points. The accuracy of this thermometer has been determined by testing and checking same with instruments tested by the National Bureau of Standards of the United States Dep't of Commerce, Washington, D. C."

DISPOSITION: 3–13–57. Default—24 thermometers of each type were turned over to the Food and Drug Administration and the remainder was destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5317. **Cellaids.** (F. D. C. No. 38958. S. Nos. 21–943/49 M, 21–951 M, 21–953 M.)

QUANTITY: 73 pkgs. at Seattle, Wash.

SHIPPED: Between 7–8–55 and 11–25–55, from Denver, Colo., by George Collingwood.

LABEL IN PART: (Pkgs.) "Cellaids * * * Calcium Fluoride [or "Calcium Phosphate," "Calcium Sulphate," "Iron Phosphate," "Potassium Chlorid," "Sodium

*See also Nos. 5301, 5308, 5312–5314, 5316.

Chlorid," "Potassium Phosphate," "Potassium Sulphate," and "Sodium Sulphate"]."

ACCOMPANYING LABELING: Book entitled "Life Chemistry or the Healing Power of Nature Fifth Edition by George Collingwood, N.D., D.B.C., D.C."

LIBELED: On or about 2-20-56, W. Dist. Wash.

CHARGE: 502 (a)—the labeling accompanying the articles, when shipped, contained the following false and misleading representations:

1. That the *calcium fluoride* was an adequate and effective treatment for soft flabby muscles, broken down elastic fiber, enlarged heart, heart leakage, floating kidney, rupture, appendicitis, varicose veins, tumors, hardening of the arteries, hard knots on the mother's breast, hard tumors, high blood pressure, abscess, asthma, tired back, inability of the uterus to expel the fetus, corns, bunions, all hard and soft swellings, cough, diphtheria, gout, hard or soft glands, piles, pus, syphilis, diseased spine, vein enlargements, paralysis, and bladder and kidney stones;

2. That the *calcium phosphate* was an adequate and effective remedy for all chronic conditions of the human body, Bright's disease, consumption or TB, catarrh, anemia, asthma, brittleness of the bones, brain fag, scanty and salty milk, cancer, cataract, cholera infantum, weakness before and after childbirth, chronic diseases of all kinds, weariness, night sweats, epilepsy, gallstones, heart disease, paralysis, rheumatism, rickets, St. Vitus' dance, decayed teeth, toothache, typhoid, ulcers, whooping cough, yellow fever, and male and female disorders;

3. That the *calcium sulphate* was an adequate and effective remedy for cleansing the body, boils, carbuncles, abscesses, pimples, all pus conditions of the surface, inflamed bladder, pus in the urine, burns, colds, chickenpox, consumption, gonorrhea, "gumboil," weakness of the liver and sickness of the stomach, sore throat, syphilis, ulcerated teeth, tonsillitis, ulcers that are not deep-seated, tubercular ulcers of the lungs, rheumatism, and cramps;

4. That the *iron phosphate* was an adequate and effective remedy for the blood stream, when there was a deficiency of iron phosphate, fever, congested conditions of any kind or place, such as an inflammation, coughs, colds, chills, pneumonia, abscess, high blood pressure, blood vessels that break easily, boils, inflammation of the brain, delirium during fevers, "wildness," meningitis, infantile paralysis, brain symptoms following fits of anger, Bright's disease, bronchitis, chickenpox, inflammation during or following labor, childbirth fever, cholera, delirium, diabetes, epilepsy, swollen, inflamed, painful glands, mild or severe inflammation, influenza, measles, inflamed nipples, piles, scarlet fever, sciatica, sleeplessness, smallpox, syphilis, yellow fever, paleness, anemia, and depression;

5. That the *potassium chloride* was an adequate and effective treatment for tonsillitis, scarlet fever, smallpox, measles, chickenpox, scalds, swollen conditions, chronic diseases in growing children, abscess, chilblains, Bright's disease, bronchitis, catarrh, croup, diabetes, epilepsy, diptheria, any swollen gland, mumps, goiter, gonorrhea, injuries, bruises, cuts, burns, pains in the liver, meningitis, pleurisy, pneumonia, scarlet fever, shingles, syphilis, whooping cough, yellow fever, and common sore throat;

6. That the *potassium phosphate* was an adequate and effective remedy for deficient brain power, nervousness, lack of energy, paralysis, palpitation of the heart, sleeplessness, insanity, abscess, anemia, asthma, blood poison of all

types where there is gangrene, Bright's disease, depression, irritability, brain fag, diphtheria, dizziness, epilepsy, fever, sluggish pulse, irregular palpitations, sinking spells, hemorrhage, hoarseness, hysteria, bronchitis, loss of voice, sciatica, spasms due to fright, spinal weakness caused by disease, syphilis, chancre, typhoid, wasting conditions, and whooping cough;

7. That the *potassium sulphate* was an adequate and effective preventive and remedy for clogging of the pores, hot, dry, and feverish condition, abscess, bronchitis, cancer, chickenpox, colds, colic, consumption, erysipelas, gonorrhea, gleet, hoarseness, influenza, measles, pneumonia, scarlet fever, all skin diseases, smallpox, indigestion, syphilis, yellow fever, and to tone up the nerves;

8. That the *sodium chloride* was an adequate and effective remedy for dropsy, languidness, drowsiness, tearfulness, sadness, chilliness, hay fever, sunstroke, fresh colds, sneezing, anemia, green sickness, atrophy, bed-wetting, bites or insect stings, excessive urination, dry or watery constipation, brain and mental conditions, blues, wandering of the mind, stupor, sleepiness, melancholy, hopelessness, dejected spirits, gloomy thoughts, weariness, exhaustion, cancer, tumors, catarrh, chickenpox, colds, consumption, delirium, dropsy, fevers, gonorrhea, hiccough, lockjaw, lumbago, bronchitis, mumps, stiff neck, piles, shingles, indigestion, sunstroke, sweats, vomiting, and whooping cough;

9. That the *sodium sulphate* was an adequate and effective remedy for cholera, chills, fever and ague, jaundice condition, yellow eyeballs, abscess, asthma, backache, bronchitis, catarrh, colic, consumption, diabetes, diarrhea, diphtheria, dizziness, erysipelas, "flu" or la grippe, ringworm, and typhoid fever and yellow fever.

DISPOSITION: 6–25–56. Default—destruction.

5318. Hoxsey treatment for internal cancer. Suit for injunction.

COMPLAINT FILED: On 7–9–57, Harry M. Hoxsey, Dallas, Tex., filed, in the District of Columbia, a complaint for preliminary injunction and permanent injunction against Marion B. Folsom, Secretary, Department of Health, Education, and Welfare, and George P. Larrick, Commissioner, Food and Drug Administration, to require the defendants to recall or modify the poster set forth below.

NATURE OF POSTER: The poster complained of is as follows:

PUBLIC
BEWARE!

WARNING AGAINST THE HOXSEY CANCER TREATMENT

Sufferers from cancer, their families, physicians, and all concerned with the care of cancer patients are hereby advised and warned that the Hoxsey treatment for internal cancer has been found worthless by two Federal courts.

The Hoxsey treatment costs $400, plus $60 in additional fees—expenditures which will yield nothing of value in the care of cancer. It consists essentially of simple drugs which are worthless for treating cancer.

The Food and Drug Administration conducted a thorough investigation of the Hoxsey treatment and the cases which were claimed to be cured. Not a single verified cure of internal cancer by this treatment has been found.

> Those afflicted with cancer are warned not to be misled by the false promise that the Hoxsey cancer treatment will cure or alleviate their condition. Cancer can be cured only through surgery or radiation. Death from cancer is inevitable when cancer patients fail to obtain proper medical treatment because of the lure of a painless cure "without the use of surgery, x-ray, or radium" as claimed by Hoxsey.

Anyone planning to try this treatment should get the facts about it.

For further information write to:
U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington 25, D. C.

NATURE OF COMPLAINT: The complaint alleged that Defendant Larrick, during the fiscal year ending 6–30–57, arbitrarily, capriciously, without regard to plaintiff's rights, and without authority of law, caused the above poster to be issued and sent for display in thousands of public buildings throughout the United States; and that the Food and Drug Administration was without power to prepare, print, and distribute such a poster without an opportunity for plaintiff to be heard.

The complaint alleged also that the printing and distribution of the above poster violated plaintiff's constitutional right in that this was accomplished without according him a hearing, at which he could have established the falsity of the claims in the above poster; that the defendants exceeded their authority in planning, printing, and distributing the above poster without an investigation of the plaintiff and his treatment; that the defendants' action was in violation of the due process clause of the Constitution; that the defendants' acts were ultra vires, and beyond the scope of their authority authorized by law, as the law and the Constitution contemplate no condemnation of an accused without a trial, and no impairment of the rights of a citizen without a hearing; and the plaintiff had suffered irreparable injury.

DISPOSITION: Following the filing of the complaint, the plaintiff, on 8–1–57, filed a motion for a preliminary injunction and a motion for the appointment of a three-judge court to hear arguments on the constitutionality of Sections 705 (a) and (b).

On 8–8–57, a motion to dismiss and for summary judgment was filed on behalf of the defendants. The motion was based on the grounds that (1) the court was without jurisdiction, as the action was against the United States which had not consented to be sued or waived its immunity; (2) the complaint failed to state a claim in that it sought to enjoin the defendants from publishing statements in their official capacity as officers of the United States Government; (3) the warning was authorized by Section 705 (b); (4) the notice originally was published in the Federal Register on 4–7–56 and the poster was merely a condensation; (5) even if the poster were a libel, equity traditionally will not enjoin the publication of a libel, public officials are not liable to civil suit for presenting the facts about law enforcement litigation to the public in the course of their official duties, and a mandatory injunction should not issue to control discretionary actions of administrative officers pursuant to authority; and (6) the statements in the poster are true and accurate in all respects.

On 10–11–57, the motions came on for argument, after which the court handed down the following opinion:

HOLTZOFF, *District Judge:* "The Food and Drug Administration has issued a circular, copies of which are being posted in post offices throughout the country, warning the public that the so-called Hoxsey cancer treatment has been found worthless insofar as internal cancer is concerned. It also warns those afflicted with cancer not to be misled by the false promise that the Hoxsey cancer treatment will cure or alleviate their condition. This action is brought by Harry M. Hoxsey who claims to have treated patients afflicted with cancer, to enjoin the Secretary of the Department of Health, Education and Welfare, and the Commissioner of the Food and Drug Administration, against the dissemination of this circular.

"The defendants claim that they are acting pursuant to the authority of the United States Code Title 21, Section 375 (b) which reads as follows:

> The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Agency.

"The plaintiff claims that this statute is unconstitutional and moves that a three-judge court be convened. He has also moved for a preliminary injunction. On the other hand the defendants move for summary judgment dismissing the complaint on the merits. The motions have been heard jointly.

"It is claimed in behalf of the plaintiff that the statute to which reference has just been made is unconstitutional as a denial of due process of law in that it does not provide for any notice or hearing, administrative or otherwise, before the Secretary disseminates information of the type described in the statute. It is elementary law, of course, that an order of an administrative agency adjudicating rights or directing someone to do or refrain from doing something must be based on a hearing after due notice. Here, however, the situation is entirely different. The defendants have made no order; they are adjudicating no rights; they are issuing no directions. What they are doing is disseminating information and warning the public against the use of certain medicines and of a certain treatment for internal cancer. There is no basis for requiring a hearing before information can be disseminated.

"But beyond that, even in the absence of this statute there would be nothing to prevent the defendants from disseminating information to the public. For example, only recently certain public officials have been urging the public to use a certain innoculation for poliomyelitis. The defendants are performing a public duty when they are urging the use of certain treatments. The only purpose of this statute is to place within the express scope of the duties of the Secretary something that was one of his implied functions.

"If, however, the contents of the circular were erroneous, then the question might arise whether they were libelous. It is a well-settled rule of equity that equity does not enjoin a libel or slander, and that the only remedy for libel or slander is an action for damages if the libelous character of a statement to which objection is made can be established. One of the leading cases on this point is the well-considered opinion of the Circuit Court of Appeals for the Second Circuit in American Malting Company vs. Keitel, 209 Fed. 351. Naturally in a libel suit the question would arise whether there is absolute or conditional privilege, and those questions are not before the court at this time.

"A three-judge court may not be convened merely because a constitutional question is raised in an action for an injunction and a preliminary injunction is applied for. The constitutional question must be a substantial one.

"The Court is of the opinion, for the reasons just stated, that there is no substantial constitutional question presented in this case, first, because the statute involved is obviously constitutional; and, second, because the question of constitutionality of that statute hardly arises since the defendants could disseminate information even without statutory authority.

"The Court will therefore deny the motion for the convening of a three-judge court and will grant the motion of defendants for summary judgment."

Appropriate orders were entered by the court.

5319. Neu-Clear Therapy Electronic Condensator (2 seizure actions). (F. D. C. Nos. 39643, 39644. S. Nos. 19–508/9 M.)

QUANTITY: 2 devices and various accessories at Portsmouth and New Boston, Ohio.

SHIPPED: 12–12–55 and 1–1–56, from Detroit, Mich., by Colo Products, Inc.

LABEL IN PART: (Device) "Neu-Clear Therapy Electronic 'Condensator' Generating 'Fluid' Electricity."

ACCOMPANYING LABELING: Booklet entitled "Holder's Electronic High-Frequency Condensator Operating Instructions."

RESULTS OF INVESTIGATION: The device consisted of an electronic, high-voltage oscillator and a group of glass electrode applicators. The electrodes were gas-filled and produced a glow discharge during application. The radio frequencies emanating were of such low power and low frequency as to have negligible absorption in the body.

LIBELED: 10–23–56, S. Dist. Ohio.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that the device was effective for locating trouble areas and toxic conditions and for determining the seriousness of the conditions; for treating all body ailments, including ailments of the eyes, ears, throat, tonsils, teeth, face, heart, lungs, liver, gallbladder, kidney, pancreas, spleen, stomach, bowels, anus, rectum, breasts, ovaries, uterus, vagina, cervix, brain, and frontal sinus; and for treating abscess, anemia, arthritis, rheumatism, paralysis, hay fever, hemorrhoids, varicose veins, leg ulcers, multiple sclerosis, mucous colitis, malnutrition, pain, influenza, indigestion, head noises, and allergic conditions due to a large variety of products.

DISPOSITION: 11–30–56. Default—destruction.

DRUG FOR VETERINARY USE

5320. King Castle Complete Minerals. (F. D. C. No. 40080. S. No. 56–719 M.)

QUANTITY: 77 50-lb. bags at Lancaster, Wis.

SHIPPED: 2–21–56, from Marion, Iowa, by Marion Feed Center.

LABEL IN PART: (Bag) "King Castle Complete Mineral * * * 1,000,000 U. S. P. Units of Vitamin D_2 Packed in Each 100 Lbs."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin D_2.

LIBELED: 4–12–57, W. Dist. Wis.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "1,000,000 U. S. P. Units of Vitamin D_2 Packed in Each 100 Lbs." was false and misleading.

DISPOSITION: 5–9–57. Default—consumption by animals.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5301 TO 5320

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1](5318) Injunction contested. Contains opinion of the court.
[2](5312) Prosecution contested.
[3](5313) Seizure contested.
[4](5308) Prosecution contested. Contains opinion of the court.

[1](5318) Injunction contested. Contains opinion of the court.
[2](5312) Prosecution contested.
[4](5308) Prosecution contested. Contains opinion of the court.

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D. D. N. J., F. D. C. 5321–5340 Issued December 1958

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5321–5340

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation and (2) criminal proceedings terminated with a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 12, 1958.*

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487698—58

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5321–5340

Adulteration, Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary or United States Pharmacopeia), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503 (b) (4), the label of the article bore the statement "Caution: Federal law prohibits dispensing without prescription," and it was a drug to which Section 503 (b) (1) did not apply.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5321. Glandular preparations. (F. D. C. No. 36806. S. Nos. 88–806/21 L.)

QUANTITY: 32 boxes, 6 cartoned 1-cc. ampuls each, of *corpora lutea soluble extract;* 11 btls., 100 5-grain Emplets each, and 19 btls., 50 5-grain tablets each, of *corpora lutea desiccated;* 30 btls., 100 5-grain Emplets each, of *ovarian residue;* 28 1-oz. btls. of *ovarian substance desiccated;* 15 boxes, 12 cartoned 1-cc. ampuls each, of *ovarian substance soluble extract;* 111 btls., 100 5-grain Emplets each, and 44 btls., 100 5-grain tablets each, of *ovarian substance desiccated;* 27 btls., 100 1/10-grain Emplets each, and 16 btls., 100 1/10-grain tablets each, of *parathyroid gland desiccated;* 4 1-oz. btls. of *pituitary body anterior lobe desiccated* and 23 btls., 100 2½-grain Emplets each, 42 btls., 100 5-grain Emplets each, 9 btls., 100 2½-grain tablets each, and 20 btls., 100 5-grain tablets each, of *pituitary body anterior lobe desiccated;* 10 1-oz. btls., 40 btls., 100 1-grain Emplets each, and 13 btls., 100 1-grain tablets each, of *pituitary body whole gland desiccated*, at Chicago, Ill.

SHIPPED: Between 8–13–53 and 3–17–54, from Detroit, Mich., by Parke, Davis & Co.

LIBELED: 5–27–54, N. Dist. Ill.

CHARGE: (502) (f) (1)—the labeling of the articles, when shipped, failed to bear adequate directions for use; and 503 (b) (4)—all articles, except the 32-box lot of *corpora lutea soluble extract* and the 15-box lot of *ovarian substance soluble extract*, bore on their labels prior to dispensing the statement "Caution: Federal law prohibits dispensing without prescription," and such articles were drugs to which 503 (b) (1) did not apply.

DISPOSITION: 4–23–57. Upon the representation of the claimant, Parke, Davis & Co., that the intrinsic value of the article was negligible, and with the consent of the claimant and the Government that a decree might be entered pursuant

to the provisions of the Federal Food, Drug, and Cosmetic Act without adjudication as to any issue of fact or law, the court entered an order directing that the article be turned over to the United States Department of Health, Education, and Welfare, pursuant to the provisions of such Act.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5322. Immun capsules (3 seizure actions). (F. D. C. Nos. 37699, 37700, 37898. S. Nos. 4–034 M, 15–959 M, 16–185 M.)

QUANTITY: 60 btls. at Seattle, Wash., 44 btls. at Pittsburgh, Pa., and 21 btls. at Spokane, Wash.

SHIPPED: Between 12–1–54 and 2–8–55, from New York, N. Y., by Universal Nutritions, Inc.

LABEL IN PART: (Btl.) "Immun Capsules Improved with Activator X Each Capsule Contains: Vitamin A (fish liver oils) 2,000 U. S. P. Units 50% Minimum daily requirement Vitamin D (fish liver oils) 200 U. S. P. Units 50% Minimum daily requirement Activator X 6 Minims Vitamin E 0.68 I. U. * * * Manufactured Exclusively for Nu-Health Laboratories, Inc., Lynbrook, New York A Nutrient Supplement with Naturally Occurring Antioxidant. Dosage: Adults And Children one capsule twice a day with meals. Contents 60 Capsules Activator X is Nu-Health Laboratories' Trade Mark for the essential unsaturated fatty acids, oleic, linoleic, linolenic, arachidonic, hexaenoic, and pantaenoid derived from mammalian oils."

ACCOMPANYING LABELING: Leaflet entitled "Read How Immun Capsules with 'Activator X' Helped Many People."

LIBELED: 3–9–55, W. Dist. Pa.; 3–15–55, W. Dist. Wash.; 3–30–55, E. Dist. Wash.

CHARGE: 502 (a)—when shipped, the labeling of the article contained the following false and misleading representations:

(a) The name "Immun Capsules" represented that the article would increase immunity to disease;

(b) The name of the ingredient "Activator X" represented that the ingredient so designated was effective to activate and make effective the nutritive elements obtained from common foods; and

(c) The leaflet represented that the article would be effective to provide immunity to disease, to increase vigor, to prolong life, and to prolong sex potency; and, further, that the article would be effective in the prevention and treatment of dental caries, colds, arthritis, joint and muscle stiffness, general debility, loss of appetite, underweight, gastritis, belching, anemia, insomnia, low blood pressure, disturbed calcium and phosphorus metabolism, impaired vision, painful menses, constipation, general fatigue, irregular heart, chest pains, and bronchitis; and

502 (f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: Nu-Health Laboratories, Inc., Lynbrook, N. Y., entered all 3 actions as claimant and petitioned for the removal of these actions to the Southern District of New York for trial. Pursuant to such petitions, the 3 seizure actions were removed and consolidated for trial in that District.

On 9–26–56, the answer and claim of Nu-Health Laboratories, Inc., were withdrawn; and on 3–8–57, a default decree providing for destruction of the article was entered.

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*See also No. 5321.

5323. Epsom salt. (F. D. C. No. 40172. S. No. 60–638 M.)

QUANTITY: 36 cases, 12 7-oz. ctns. each, and 24 cases, 12 1-lb. ctns. each, at Hermon, Maine, in possession of Byron H. Smith & Co.

SHIPPED: From Midland, Mich.

LABEL IN PART: "Three Crow Brand Epsom Salts U. S. P. * * * Packed by The Atlantic Spice Co., Bangor, Maine."

RESULTS OF INVESTIGATION: The product was shipped from Michigan in 100-lb. bags, and upon receipt by Byron H. Smith & Co., it was repacked by that firm into the cartons and cases described above.

LIBELED: 4–23–57, Dist. Maine.

CHARGE: 501 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use since no directions for use or dosage directions were given; and 502 (f) (2)—the article was essentially a laxative, and its labeling failed to warn that frequent or continued use of the article may result in dependence upon laxatives to move the bowels and that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present.

DISPOSITION: 6–2–57. Default—delivered to a charitable institution.

5324. First aid kits. (F. D. C. No. 39428. S. Nos. 47–912/3 M.)

QUANTITY: 637 *first aid kits* at New York, N. Y.

SHIPPED: 6–26–56 and 7–3–56, from Tulsa, Okla., and St. Louis, Mo.

RESULTS OF INVESTIGATION: Examination showed that a portion of the *first aid kits* consisted of a canvas pouch containing, among other items, a bottle of 100 *halazone tablets*. Examination showed further that another portion of the first aid kits consisted of a leather pouch holding, among other items, a tube of *boric acid ointment* and a bottle of 100 *halazone tablets*.

Analysis showed that the *halazone tablets* contained from 18 to 80 percent of the declared amount of halazone, whereas the National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone. The label of the *boric acid ointment* bore no directions for use.

LIBELED: 9–6–56, S. Dist. N. Y.

CHARGE: 501 (b)—the strength of the *halazone tablets*, while held for sale, differed from the standard for halazone tablets set forth in the National Formulary; and 502 (f) (1)—the labeling of the *boric acid ointment* failed to bear adequate directions for use.

DISPOSITION: 12–18–56. Default—destruction.

5325. Niagara devices. (F. D. C. No. 39678. S. No. 56–387 M.)

QUANTITY: 5 *Niagara Hand Units*, 2 *Niagara Thermo-Cyclopads*, 1 *Deluxe Niagara Thermo-Cyclopad* with *Niagara Hand Unit*, and 1 *Deluxe Niagara Thermo-Cyclopad* without *Niagara Hand Unit*, at Minneapolis, Minn., in possession of Ralph E. Dixon.

SHIPPED: 9–19–56, from Adamsville, Pa., by Niagara Midwestern Corp.

LABEL IN PART: (Metal box attached to *Niagara Hand Unit*) "Niagara * * * Hand Unit Model No. 1 * * * Niagara Manufacturing and Distributing Corp. Adamsville, Penn. U. S. A."; (carton containing *Niagara Thermo-Cyclopad*) "The New Niagara Thermo-Cyclopad * * * This carton contains 1-Niagara Thermo-Cyclopad * * * Manufactured and distributed by the Niagara Manufacturing and Distributing Corp. Adamsville,

Pa."; (metal box attached to the *Niagara Thermo-Cyclopad*) "Thermo-Cyclopad Model 10."

ACCOMPANYING LABELING: Copies of a brochure designated "General Directions For Use" and leaflets designated "Miracle of Science . . . At Last . . . Two of mankind's greatest healers" and "Miracle Science . . . Niagara Cyclo-Massage."

RESULTS OF INVESTIGATION: The *Niagara Thermo-Cyclopad* consisted of a rectangular pad with an electrical attachment at one end. The pad was approximately 23½ inches long, 15½ inches wide, and 1¾ inches deep. The electrical attachment had a control box connected to it by means of electrical wiring, and the control box had a connection for plugging into household current. In operation, the pad could be heated by means of electric current, and it also could be made to vibrate by means of its built-in electrical mechanism.

The *Niagara Hand Unit* consisted of a rounded metallic object approximately 10 inches long and 3½ inches in diameter at the largest part. It had an electrical wire connector and control box which, when plugged into the household current, caused the unit to vibrate. The slender end of the *Niagara Hand Unit* had a rubber cup attachment.

LIBELED: 11–15–56, Dist. Minn.

CHARGE: 502 (a)—the labeling accompanying the devices, when shipped, contained false and misleading representations that the devices provided an adequate and effective treatment for impaired circulation, arthritis, bursitis, rheumatism, lumbago, numbness of the extremities, fibrositis, nervous tension, muscle spasm, impaired muscle and joint mobility, insomnia, and renewing one's life; and 502 (f) (1)—while held for sale, the labeling of the devices failed to bear adequate directions for use in preventing and overcoming calcium deposits; in overcoming "locked joints" and sinus congestion; in enabling diabetics to stop taking insulin; in overcoming prostate trouble, asthma, hay fever, respiratory conditions, and baldness, which were the conditions for which the devices were intended and for which they were recommended orally by Ralph E. Dixon in promoting the sale of the devices.

DISPOSITION: 1–2–57. Default—delivered to the Food and Drug Administration.

5326. Schlessing Ultrasoniseur devices. (F. D. C. No. 33565. S. No. 18–735 L.)

QUANTITY: 75 devices at Los Angeles and Santa Monica, Calif.

SHIPPED: Between 7–1–51 and 9–4–52, from St. Louis, Mo., by A. Schlessing & Co., Inc.

ACCOMPANYING LABELING: Pamphlets entitled "Therapeutics by Ultrasonics"; leaflets entitled "Please Read Carefully. The Schlessing Ultrasoniseur . . ." and "that they may WALK again . . ."; sheets entitled "Reports on Ultrasonic Physical Medicine from American Users"; form letters headed "Dear Doctor:"; and guarantees and order blanks regarding Schlessing Ultrasoniseur.

LIBELED: 9–5–52, S. Dist. Calif.

CHARGE: 501 (c)—the strength of the devices, when shipped and while held for sale, differed from, and their quality fell below, that which they purported and were represented to possess since their ability to produce total sound output (ultrasonic) differed materially from the ability which they were represented to possess and the output meter (dosimeter) did not accurately gauge the energy density output of the devices; 502 (a)—the labeling of

the devices, when taken as a whole as well as through specific claims, and in the setting in which it was presented, contained false and misleading representations that the devices would provide an adequate and effective treatment for the cure of "abscesses, arthritis, arthrosis deformans, asthma bronchiale, morbus bechterew, bronchiektasy, claudicato intermittens, furunculosis, sciatica, carbunculosis, lumbago, mastitis, myalgia, panaritia, paronychosis, periarthritis humeroscapularis, phlegmones, prostata hypertrophy, sinusitis maxillaris, ulcus cruris, effusions of the joints, abscesses of perspiratory glands, gingivitis, stomatitis, paradentosis, pulpitis, infiltrations, especially granulomes, bursitis, Dupuytren's contracture, endangitis obliterans, fistulae, lymphangitis, paronychia, polyarthritis rheumatica, postoperative pains, morbus raynaud, tendovaginitides, trigeminal neuralgiae, thrombophlebitides, ulcus ventriculi, kidney stones, spinal arthritis, gum boils, kidney colic, gastric ulcer, and asthma"; 502 (a), the following statements contained in the labeling of the devices were misleading: in leaflets entitled "Please Read Carefully," "This Machine Is Absolutely Safe," "that they may WALK again . . .," "Is the Schlessing Ultrasoniseur Difficult to Operate? Not at all. The technique if [sic] the very simplest. No special skill, no involved instructions and no long experience is necessary to use the Schlessing Ultrasoniseur properly. Is the Schlessing Ultrasoniseur Safe? Yes. With ordinary precautions. Ultrasoniseur treatments are absolutely painless. There are no contra-indications. No danger of deep burns, tissue damage or irritation. Equally important, there are no possible harmful effects to the person administering treatment."; and 502 (f) (1)—the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended.

DISPOSITION: 10–22–52. Consent—claimed by A. Schlessing, St. Louis, Mo. The above-described accompanying labeling was delivered to the Food and Drug Administration, and the devices were released under bond to the claimant to be brought into compliance with the law.

Following the entry of the decree, the claimant arranged to ship back to St. Louis, Mo., 47 devices that actually were seized under the libel. Thereafter, 6 of the devices were reconditioned from a physical standpoint to the satisfaction of the Department of Health, Education, and Welfare; and reconditioning of the other 41 devices was suspended until a final decision was made regarding the legality of claimant's proposed method of distribution of the 6 reconditioned devices to licensed California chiropractors, in whose possession the devices were seized at the outset of the libel action. The Department refused to release the devices for such distribution; and on 5–24–54, the claimant filed with the United States District Court for the Southern District of California a motion to compel administrative approval of claimant's proposed method of distributing the devices.

On 2–10–55, after a hearing in the matter, the district court issued its findings of fact and conclusions of law and an order denying the claimant's motion. On 5–17–55, the district court filed a final order directing the claimant to return the devices to the United States marshal and directing the marshal to offer the devices for sale under conditions to be approved by the Department of Health, Education, and Welfare. The claimant appealed to the United States Court of Appeals for the 9th Circuit; and, on 9–24–56, the following opinion was handed down by that court:

FEE, *Circuit Judge:* "This is a review of the denial of a motion by Schlessing to compel administrative approval of a method of distributing certain devices

designated as 'The Schlessing Ultrasoniseur' in the manner proposed by him. All these devices had been condemned in an action for the seizure of seventy-five of these devices prosecuted in the United States District Court for the Southern District of California. The six Ultrasoniseurs here in question were among those sequestered in that action.

"Schlessing, as claimant, on October 22, 1952, agreed to a Consent Decree of Condemnation. By its terms all of these devices then in possession of the court, to the number of forty-seven, were adjudged adulterated and misbranded as alleged in the libel and were condemned under 21 U. S. C. A. § 384 (a). These articles, upon condemnation, were subject to destruction. However, in accordance with the stipulation for consent to the entry of such decree, it was therein provided that claimant was allowed the privilege of distributing such articles when released in the discretion of the administrative body. One provision in the consent decree declares in substance that the claimant shall not distribute the devices until he shall have obtained a written release from the head of the agency. Specifically, it was agreed and the Consent Decree of Condemnation provided that:

> Claimant shall make no distribution of said articles or any part of them except in strict accord with such term and conditions as may be included in said written release.

The decree also contains other provisions:

> Ultrasonic therapy cannot be employed safely and efficaciously by the layman in self-medication, but requires competent supervision in its administration. Adequate directions for unsupervised lay use cannot be written for ultrasonic devices, within the meaning of 21 U. S. C. 352 (f) (1). Interstate distribution which would not violate the Federal Food, Drug, and Cosmetic Act must therefore comply with the regulations which exempt devices from bearing adequate directions for use in their labeling. (21 C. F. R. § 1.106, as amended.) One provision of these regulations exempts a device which is shipped to "a practitioner licensed by law to * * * use or direct the use of the device." (21 C. F. R. § 1.106 (e))

Also:

> The Claimant shall not sell or dispose of said articles or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State * * * in which they are sold or disposed of.

"The Consent Decree of Condemnation further expressly retains in the court the jurisdiction to issue further orders, which permitted the court to order destruction of all of these devices on the same terms as could have been originally done.

"The District Court heard the motion and received a stipulation as to the issue to be tried, as follows:

> Is a Chiropractor, who is licensed under the California Chiropractic Act, a practitioner licensed by law to use or direct the use of devices such as the six reconditioned ultrasonic therapeutic devices involved in this case, so as to satisfy the requirements of 21 C. F. R. § 1.106 (e), as amended, and exempt the devices from complying with 21 U. S. C. 352 (f) (1)?

Upon this basis, the District Court issued findings and conclusions and a decree requiring claimant to return the devices at his own expense to be offered for sale 'in such manner and under such conditions as shall be approved by the Los Angeles District of the Food and Drug Administration, Department of Health, Education, and Welfare.'

"The decree must be affirmed. Upon condemnation, the District Court had power and authority to have these devices sold or destroyed under conditions such as are here laid down. The claimant may have entered into a contract which he now regrets, but the terms of the consent decree are clear and unambiguous. He made the release of the devices by the agency the sole criterion. He agreed that the court could issue further orders. He cannot now claim that, if he had known the terms of release would be what they now turn out to be, he would never have made the bargain.

"The practice of medicine and chiropractic in California is regulated by the legislature and administrative boards of the state. There is no law, regulation or decision of that state which forbids the shipment of an Ultrasoniseur into its boundaries. It is a mooted question whether a chiropractor can use such a device, but it is one for the courts and agencies of California to regulate. The agency has no jurisdiction or authority to attempt to regulate the practice of medicine or chiropractic in that state.

"The trial court was led into passing on a matter of state law and administrative discretion of the legislature and the agencies of California. Therefore, the final judgment and decree is affirmed, but the court is constrained to eliminate from the findings and conclusions all references to the nature of chiropractic, ultrasonic therapy and the practice of medicine and of chiropractors in California and all other matters which are here disapproved. The findings relating to the consent decree and the agreement not to ship the machines without release by the administrative agencies and the agreement that the court should make further orders carrying out the original condemnation and sale are left standing.

"Remanded, affirming the final decree herein. The modifications of the findings and conclusions need not be physically made. The appeal is dismissed."

Following the above opinion, the case was remanded to the district court; and, on 11–27–56, pursuant to the order of the district court, the United States marshal destroyed the 47 devices which had been seized.

PRESENCE OF A HABIT-FORMING NARCOTIC WITHOUT WARNING STATEMENT

5327. Amobarbital sodium and phenobarbital sodium. (F. D. C. No. 39189. S. Nos. 17–585 M, 21–661 M, 21–678 M.)

INDICTMENT RETURNED: 2–18–57, E. Dist. Pa., against Milton A. Calesnick, t/a Addison Laboratories, Philadelphia, Pa.

ALLEGED VIOLATION: On 4–14–55, the defendant caused to be given to a firm engaged in the business of shipping drugs in interstate commerce an invoice containing a guaranty that the ampuls of *phenobarbital sodium* and *amobarbital sodium* covered by the invoice were not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 4–14–55, the defendant caused to be delivered to the holder of the guaranty, at Philadelphia, Pa., under the above invoice, ampuls of *phenobarbital sodium* which were adulterated and ampuls of *amobarbital sodium* which were adulterated and misbranded.

In addition, the defendant caused to be shipped, on 4–22–55, from Pennsylvania to Virginia a number of ampuls of *amobarbital sodium* which were adulterated and misbranded.

LABEL IN PART: (Ampuls) "Amobarbital Sodium 7½ gr. [or "3¾ gr."] Sterile–Intravenous" and "5 cc. Ampoule Sodium Phenobarbital Contains: 2 Grains–Dry Powder–Sterile–Intramuscular."

RESULTS OF INVESTIGATION: Examination of the *amobarbital sodium* showed that some ampuls contained more and some ampuls contained less than the labeled amount of amobarbital sodium. Examination of the *phenobarbital sodium* showed that it contained more than the labeled amount of that ingredient.

CHARGE: *Phenobarbital sodium.* 501 (b)—the article purported to be and was represented as "Sterile Phenobarbital Sodium," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium; and its strength, when shipped, differed from the official standard since the average weight of the content of phenobarbital sodium per ampul failed to comply with the standard specified in the compendium.

Amobarbital sodium. 501 (b)—the article purported to be and was represented as "Amobarbital Sodium," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength, when shipped, differed from the official standard since the average weight of the content of *Amobarbital Sodium* per ampul failed to comply with the standard specified in the compendium; and 502 (d)—the article contained amobarbital sodium, a chemical derivative of barbituric acid, which has been designated by regulations as habit forming; and the label of the article failed to bear the statement "Warning—May be habit forming."

PLEA: Guilty.

DISPOSITION: 6–17–57. Defendant fined $2,000 and placed on probation for 3 years.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

5328. Serutan. (F. D. C. No. 39807. S. Nos. 35–501 M, 35–504 M.)

QUANTITY: 24 doz. boxes, 9 oz. each, at Cincinnati, Ohio.

SHIPPED: Between 4–1–56 and 9–28–56, from Newark, N. J.

LIBELED: 12–6–56, S. Dist. Ohio.

CHARGE: 501 (a) (2)—contained insects while held for sale.

DISPOSITION: 1–11–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5329. Digitalis tablets. (F. D. C. No. 40163. S. No. 35–064 M.)

QUANTITY: 1 drum containing 67,300 tablets at Cleveland, Ohio.

SHIPPED: 8–3–56, from New York, N. Y.

LABEL IN PART: (Drum) "Tablets Digitalis Leaves Private Formula #1078 U. S. P. 1½ gr. * * * 17214 The Superior Pharmacal Co., Dayton, Ohio."

RESULTS OF INVESTIGATION: The article was shipped from New York, N. Y., as a bulk powder; and, after receipt in Dayton, Ohio, it was made into tablets by Superior Pharmacal Co. and shipped to Cleveland, Ohio. Examination showed that the tablets contained not more than 67.6 percent of the declared amount of digitalis, or 1.01 grains of U. S. P. digitalis per tablet. The United States Pharmacopeia provides that digitalis tablets contain the labeled amount of digitalis.

LIBELED: 4–11–57, N. Dist. Ohio.

*See also Nos. 5324, 5326, 5327, 5338, 5340.

CHARGE: 501 (b)—the article, while held for sale, purported to be a drug, "Digitalis Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 5–13–57. Default—destruction.

5330. Digitoxin powder. (F. D. C. No. 40111. S. No. 56–160 M.)

QUANTITY: 2 25-gram btls. at Chicago, Ill.

SHIPPED: 1–16–57, from New York, N. Y., by European Chemical Co., Inc.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * Assay: Digitoxin 99.10% Loss on drying 0.62%."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 85 percent of digitoxin when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay result be not less than 90 percent.

LIBELED: 3–28–57, N. Dist. Ill.

CHARGE: 501 (b)—The article, when shipped, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4–23–57. Default—destruction.

5331. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40121. S. Nos. 38–204/5 M.)

QUANTITY: 1 6-gram btl. and 1 40,000-tablet drum at St. Louis, Mo.

SHIPPED: 12–14–56, from New York, N. Y., by H. Reisman Corp.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * For Manufacturing, Processing or Repacking"; (drum) "0.2 mg. C. T. Digitoxin."

RESULTS OF INVESTIGATION: The above tablets were prepared by the consignee from a portion of the bulk *digitoxin powder* shipped on the above date.

Examination showed that the powder contained not more than 83.5 percent digitoxin and that the tablets contained not more than 0.156 milligram of digitoxin per tablet when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay results be not less than 90 percent of the labeled amount of digitoxin.

LIBELED: 4–4–57, E. Dist. Mo.

CHARGE: 501 (b)—the article, when shipped and while held for sale, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4–30–57. Default—destruction.

5332. Digitoxin tablets. (F. D. C. No. 40162. S. No. 38–211 M.)

QUANTITY: 34,772 tablets at St. Louis, Mo.

SHIPPED: 7–6–56 and 11–26–56, from New York, N. Y.

LABEL IN PART: "109a Compressed Tablets Digitoxin, 0.2 mg. Each Tablet Contains: Digitoxin, U. S. P. * * * 0.2 mg."

RESULTS OF INVESTIGATION: The tablets were prepared from bulk digitoxin powder which had been shipped to St. Louis, Mo., as described above.

Examination showed that the tablets contained not more than 0.115 milligram of digitoxin per tablet, which equaled 57.3 percent of the declared amount of digitoxin.

LIBELED: 4–11–57, E. Dist. Mo.

CHARGE: 501 (b)—while held for sale, the strength of the tablets differed from, and their quality fell below, the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 5–10–57. Default—destruction.

5333. Del-Caps 15 capsules. (F. D. C. No. 40065. S. No. 38–293 M.)

QUANTITY: 20 1,000-capsule btls. at St. Louis, Mo.

SHIPPED: 1–25–57, from Rensselaer, N. Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Btl.) "Del-Caps 15 * * * Each capsule contains: Dextro Amphetamine Sulfate 15 mg."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 11.5 milligrams of dextro-amphetamine sulfate per capsule.

LIBELED: 3–21–57, Dist. Mo.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each capsule contains: Dextro Amphetamine Sulfate 15 mg." was false and misleading.

DISPOSITION: 4–16–57. Default—destruction.

5334. Neo-Colivone. (F. D. C. No. 39754. S. No. 62–688 M.)

QUANTITY: 35 100-cc. vials at Lakewood, N. J.

SHIPPED: 10–15–56, from New York, N. Y., by Vincent Christina & Co.

RESULTS OF INVESTIGATION: Examination showed that the article contained about 70 percent of the declared amount of vitamin B_1.

LIBELED: 1–16–57, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 25 milligrams of vitamin B_1 (thiamine HCl) per cubic centimeter; and 502 (a)—the label statement "each cc. contains: Thiamine Hcl 25 mg." was false and misleading.

DISPOSITION: 2–19–57. Default—destruction.

5335. Vitamin tablets. (F. D. C. No. 40167. S. No. 59–353 M.)

QUANTITY: 10 250-tablet btls. and 347 28-tablet btls. at Philadelphia, Pa.

SHIPPED: On an unknown date, from Brooklyn, N. Y., by Sweet Laboratories.

LABEL IN PART: "Halbee-G High Potency * * * chewing (gum) tablets Ingredients: Vitamin B_1 10 mg. * * * Vitamin B_{12} 25 mcg."

RESULTS OF INVESTIGATION: Examination showed that the article contained less than 5 mg. of vitamin B_1 per tablet.

LIBELED: 4–17–57, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 10 mg.of vitamin B_1 per tablet; and 502 (a)—the bottle label contained false and misleading representations that the article was effective in the treatment of chronic diarrhea and celiac disease.

DISPOSITION: 5–21–57. Default—destruction.

5336. Halazone tablets. (F. D. C. No. 40168. S. No. 63–029 M.)

QUANTITY: 9 cases containing a total of 892 btls. at New York, N. Y.

SHIPPED: 1–22–54, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "100 Water Purification Tablets for Purifying Drinking Water in Canteens * * * Halazone N. N. R. * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium borate and chloride."

RESULTS OF INVESTIGATION: Examination showed that the article contained from 0.5 percent to 91.5 percent of the labeled amount of halazone.

LIBELED: 4–23–57, S. Dist. N. Y.

CHARGE: 501 (b)—the strength of the article, while held for sale, differed from the standard for halazone tablets set forth in the National Formulary.

DISPOSITION: 5–22–57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5337. Fenugreek seed, yerba maté, and toasted yerba maté. (F. D. C. No. 39004. S. Nos. 40–035 M, 40–038/9 M, 40–053/8 M.)

QUANTITY: 1 170-lb. drum, 1 154-lb. drum, 8 10-oz. pkgs., and 48 2½-oz. pkgs. of *fenugreek seed;* 27 50-lb. boxes, 1 25-lb. drum, 53 1-oz. pkgs., and 49 6½-oz. pkgs. of *yerba maté;* 41 78-lb. boxes, 1 35-lb. drum, 25 1-oz. pkgs., and 19 6½-oz. pkgs. of *toasted yerba maté*, at Hammond, Ind., in possession of Indiana Botanic Gardens.

SHIPPED: Between 4–5–55 and 2–29–56, from North Bergen, N. J., Jersey City, N. J., Chicago, Ill., and Curitiba, Brazil.

LABEL IN PART: (Pkg.) "Fenugreek (Trigonella Foenum Graecum) Part used—The seeds"; "Yerba Mate (Dex Paraguensis) Other Common Names: Jesuit's Tea, Brazil Tea, Jerusalem Tea or Mate, Paraguay Tea Part used—The leaves"; "T-Mate (Toasted Yerba Mate) (Llex Paraguensis) Other Common Names: Jesuit's Tea, Brazil Tea, Jerusalem Tea or Mate, Paraguay Tea Part used—The leaves."

ACCOMPANYING LABELING: Booklets entitled "Herbal Catalog" and the 1948, 1951, 1952, 1955, and 1956 editions of a booklet entitled "The Herbalist Almanac."

RESULTS OF INVESTIGATION: The articles were shipped in interstate commerce in bulk; and, upon their receipt, the consignee repacked portions of the articles into packages labeled as described above. The booklets were printed locally for the consignee and were distributed to former and prospective customers to promote the sale of the various products advertised in them.

LIBELED: 3–29–56, N. Dist. Ind.

*See also Nos. 5322, 5325, 5326, 5333–5335.

CHARGE: 502 (a)—the labeling accompanying the articles, while held for sale, contained the following false and misleading representations:

1. That the *fenugreek seed* had the same composition and properties as cod liver oil; that it served as an adequate substitute for cod liver oil in nutritive value and for medicinal use; and that it was effective in the treatment of scrofula, rickets, anemia, and debility following infectious diseases; and

2. That the *yerba maté* and *toasted yerba maté* were a "miracle herb"; that their use would give one strength and endurance, produce mental exhilaration, bodily comfort, and refreshment without subsequent depression; that their use would facilitate digestion without disturbing sleep; that they were soothing to the nerves; that they would relieve physical or mental strain; that they would reduce the appetite; that they were an effective treatment for "dizzy spells," asthma, sciatic rheumatism, and nervousness; that they would give the user strength and pep; and that they would enable one to do a great deal of work with little food.

DISPOSITION: 9–7–56. Default—portion of booklets delivered to Food and Drug Administration and remainder, together with the drugs, destroyed.

5338. D.A.G. antiseptic and Dikkers veterinary antiseptic. (F. D. C. No. 39733. S. Nos. 24–025/6 M.)

QUANTITY: 18 1-pt. btls. of *D.A.G. antiseptic* and 90 4-oz. and 24 1-pt. btls. of *Dikkers veterinary antiseptic* at Phoenix, Ariz.

SHIPPED: 11–13–56, from Los Angeles, Calif., by Dikkers Biochemical Laboratory.

LABEL IN PART: (Btl.) "D.A.G. * * * Antiseptic * * * For minor irritations, cuts, bruises, burns. Contains: Iodophenol in a natural seaweed base. Directions: Apply to affected surface or use wet dressing. As a gargle use full strength. Do not dilute. Sold to Doctors only. Manufactured by Dikkers Biochemical Laboratory, Los Angeles, California" and "Dikkers Veterinary Antiseptic. Non Toxic. Non irritant. Contains: Iodophenol in a natural chondrus base. Caution: To be dispensed only by or on the prescription of a veterinary. Manufactured by Dikkers Biochemical Laboratory, Los Angeles, California."

ACCOMPANYING LABELING: Leaflets entitled "D.A.G. Dikkers Antiseptic and Germicide" and "D.A.G. A Therapeutic Seaweed Extract with Tri-Iodophenols. An Ethical Product for the Dental Profession."

RESULTS OF INVESTIGATION: Analysis showed that the articles were contaminated with viable organisms and were not antiseptic.

LIBELED: 1–10–57, Dist. Ariz.

CHARGE: 501 (c)—when shipped, the strength of the articles differed from, and their purity and quality fell below, that which they purported and were represented to possess; and 502 (a)—the statement on the labels of the articles, when shipped, namely, "Antiseptic," was false and misleading, and the labeling accompanying the articles, when shipped, contained the following false and misleading representations:

(1) That the *D.A.G. antiseptic* was effective as an antiseptic in oral hygiene, peridontal diseases, Vincent's infection, pyorrhea, gingivitis, dermatology, eye, ear, nose, and throat conditions, proctology, genitourinary conditions, gynecology, internal medicine, and surgery; and

(2) That the *Dikkers veterinary antiseptic* should be limited to use under the supervision of a veterinarian.

DISPOSITION: 3–7–57. Default—destruction.

5339. Sun-Kraft Dual Ray lamp. (F. D. C. No. 39258. S. No. 52–303 M.)

QUANTITY: 318 devices at Brooklyn, N. Y.

SHIPPED: 3–26–56, from Philadelphia, Pa., by Lawrence Sales Corp.

LABEL IN PART: (Base of device) "Sun-Kraft Inc. Chicago U. S. A. 12246"; (plate attached to device) "Model H–1 Sun-Kraft Inc."

ACCOMPANYING LABELING: Booklet entitled "Operation of Your Dual Ray."

RESULTS OF INVESTIGATION: Examination showed that the device consisted of a cold quartz type lamp mounted on a metallic base and equipped with a timing mechanism and reflector. This type of lamp emits ultraviolet and infrared radiations.

LIBELED: 5–28–56, E. Dist. N. Y.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that the device provided an adequate and effective treatment for calcium deficiency, acne, psoriasis, many variations of eczema, scalp conditions, skin tuberculosis, skin ulcers, slow healing wounds, arthritis, rheumatism, neuritis, neuralgia, sinusitis, conjunctivitis, certain forms of inflammation of the middle ear, bronchitis, and skin abscesses; and that it was effective for the prevention of rickets.

DISPOSITION: 12–17–56. Consent—claimed by Professional Surplus Co., Inc., Brooklyn, N. Y., and relabeled in accordance with the Act.

DRUG FOR VETERINARY USE*

5340. Dr. Mayfield Vitalcin. (F. D. C. No. 40069. S. No. 56–505 M.)

QUANTITY: 3 drums, 100 lbs. each, at Sleepy Eye, Minn.

SHIPPED: Between 1–23–57 and 2–4–57, from Charles City, Iowa, by Dr. Mayfield Laboratories.

LABEL IN PART: (Drum) "Dr. Mayfield Vitalcin, a Multi-Vitamin Supplement for use in Poultry and Swine Feeds * * * Active Ingredients: Each Pound Contains * * * Riboflavin 480 mg. * * * Vitamin C * * * 1800 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 80 percent of the declared amount of riboflavin and less than 15 percent of the declared amount of vitamin C.

LIBELED: 3–29–57, Dist. Minn.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each Pound Contains * * * Riboflavin 480 mg. * * * Vitamin C * * * 1800 mg." was false and misleading.

DISPOSITION: 5–17–57. Default—destruction.

*See also No. 5338.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5321 TO 5340

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5326) Seizure contested. Contains opinion of the court.

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U. S. GOVERNMENT PRINTING OFFICE: 1938

D. D. N. J., F. D. C. 5341–5380 Issued December 1958

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5341–5380

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 18, 1958.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

5341. (F. D. C. No. 40156. S. Nos. 62–248 M, 62–257 M, 62–541 M.)

INFORMATION FILED: 7–24–57, Dist. N. J., against **Angelo Mercuro, t/a Park Pharmacy, Orange, N. J.**

CHARGE: Between 1–8–57 and 1–24–57, *Bicillin tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber, and *Butazolidin tablets* and *penicillin-bacitracin troches* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–6–57. $250 fine and probation for 5 years.

5342. (F. D. C. No. 39339. S. Nos. 1–715/6 M, 1–733/4 M.)

INFORMATION FILED: 12–12–56, M. Dist. Ga., against **Madison L. NeSmith, t/a Fort Valley Truck Stop, Fort Valley, Ga., and James C. Swearingane (employee).**

CHARGE: Between 5–21–55 and 5–29–55, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–15–57. Each defendant placed on probation for 5 years, conditioned that NeSmith pay $250 fine and Swearingane pay $100 fine.

5343. (F. D. C. No. 40009. S. Nos. 40–163 M, 56–101/5 M.)

INFORMATION FILED: 4–23–57, N. Dist. Ind., against **Fanny Mejean, t/a Babe's Truck Stop and also t/a Phyllis & Cheryl Junction, Chesterton, Ind.**

CHARGE: Between 4–5–56 and 11–1–56, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 7–16–57. Sentence of 3 years in jail suspended and probation for 2 years.

5344. (F. D. C. No. 40147. S. No. 39–156 M.)

INFORMATION FILED: 6–13–57, S. Dist. Fla., against **Johnson's Prescription Pharmacy (a partnership), Belleview, Fla., and Anard H. Johnson (partner).**

CHARGE: On 8–8–56, *Benzedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10–29–57. Fine of $200 against defendants jointly.

5345. (F. D. C. No. 40014. S. Nos. 34–692 M, 34–695/6 M, 55–602 M.)

INFORMATION FILED: 8–28–57, S. Dist. Ind., against **Judson O. Clark, t/a J. O. Clark Pharmacy, Indianapolis, Ind.**

CHARGE: Between 8–6–56 and 9–6–56, *pentobarbital sodium capsules* were dispensed twice and *Benzedrine Sulfate tablets* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–31–57. Fine of $1,000, plus costs, and sentence of 1 year in jail. Jail sentence suspended and defendant placed on probation for 1 year.

5346. (F. D. C. No. 39990. S. Nos. 27–984 M, 27–986/7 M, 27–989/90 M, 39–545 M.)

INFORMATION FILED: 4–4–57, S. Dist. Ga., against **John F. Mullis and Frank Edward Johnson (partners in the partnership of Johnson Pharmacy), Alma, Ga.**

CHARGE: Between 6–26–56 and 8–20–56, *amphetamine sulfate tablets* were dispensed 5 times and *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8–29–57. Each defendant fined $500 and placed on probation for 4 years.

5347. (F. D. C. No. 39340. S. No. 1–443 M.)

INFORMATION FILED: 2–7–58, N. Dist. Ga., against **Charlton T. Ellis (pharmacist for Brookhaven Pharmacy), Atlanta, Ga.**

CHARGE: On 3–21–56, *tablets containing, among other ingredients, a mixture of pentobarbital and methamphetamine hydrochloride* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–17–58. Defendant fined $500 and placed on probation for 2 years.

5348. (F. D. C. No. 39985. S. Nos. 39–243 M, 39–246 M, 39–249 M.)

INFORMATION FILED: 4–29–57, M. Dist. N. C., against **Culas Roberson, t/a Tri-City Pharmacy, Spray, N. C., and Alvis Kallam (employee) and Thomas Reid Cole (pharmacist).**

CHARGE: Between 8–13–56 and 8–20–56, *pentobarbital sodium capsules* were dispensed 3 times upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty by Roberson to the 3 counts of the information and by Kallam and Cole to counts 1 and 2, respectively.

DISPOSITION: 6–5–57. Culas Roberson, t/a Tri-City Pharmacy, was fined $750; Roberson, Kallam, and Cole were placed on probation for 2 years.

5349. (F. D. C. No. 39986. S. Nos. 39–242 M, 39–634 M, 39–642 M.)

INFORMATION FILED: 4–29–57, M. Dist. N. C., against **Spray Drug Co. (a partnership), Spray, N. C., and Oscar W. Mills (partner and pharmacist) and Sherman E. Mills (partner).**

CHARGE: Between 8–9–56 and 8–21–56, *Metandren Linguets* were dispensed twice without a prescription, and *secobarbital sodium capsules* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6–5–57. Partnership—$750 fine; individuals placed on probation for 2 years.

5350. (F. D. C. No. 39403. S. Nos. 49–863 M, 49–865/6 M, 49–889 M, 49–893 M, 49–895 M, 50–224 M.)

INFORMATION FILED: 6–5–57, Dist. Mass., against **Leon C. Schlosberg, t/a Hospital Pharmacy of Boston, Boston, Mass., and Louis Meltzer (pharmacist).**

CHARGE: Between 7–9–56 and 8–1–56, *dextro-amphetamine sulfate tablets* were dispensed three times, *Gantrisin tablets* were dispensed twice, and *Butazolidin tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber; and *Candicillin troches* were dispensed once without a prescription.

PLEA: Guilty by Schlosberg to the 7 counts of the information and by Meltzer to 4 counts.

DISPOSITION: 3–31–58. Schlosberg fined $750, given jail sentence of 6 months, which was suspended, and placed on probation for 2 years; Meltzer fined $250 and placed on probation for 1 year.

5351. (F. D. C. No. 40140. S. Nos. 43–429 M, 43–438 M.)

INFORMATION FILED: 7–9–57, E. Dist. Mo., against **Charles E. Gibson, St. Louis, Mo.**

CHARGE: Between 10–6–56 and 12–15–56, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–26–57. Defendant sentenced to 1 year in jail.

5352. (F. D. C. No. 40020. S. Nos. 52–795 M, 52–798/9 M.)

INFORMATION FILED: 4–18–58, S. Dist. N. Y., against **Benjamin Marx, t/a Marx Pharmacy, Elmsford, N. Y.**

CHARGE: Between 9–20–56 and 10–3–56, *dextro-amphetamine sulfate tablets*, *secobarbital sodium capsules*, and *Seconal Sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–26–58. Defendant fined $750 and placed on probation for 1 day.

5353. (F. D. C. No. 40011. S. Nos. 47–048/9 M, 47–051/3 M, 47–056/9 M.)

INFORMATION FILED: 5–29–57, Dist. N. J., against **Medford Pharmacy, Inc., Medford, N. J., and Philip S. Willingmyre (president) and Samuel J. Chud (pharmacist).**

CHARGE: Between 8–22–56 and 9–17–56, *Dexedrine Sulfate tablets* (counts 1, 3, 4, and 6) were dispensed 4 times and *Tuinal pulvules* (counts 2 and 7) were dispensed twice upon requests for prescription refills without authorization by the prescriber; and *tetracycline hydrochloride capsules* (count 5) were dispensed once and *capsules of apiol and ergotin with aloin and pennyroyal* (counts 8 and 9) were dispensed twice without a prescription.

PLEA: Guilty by corporation and Willingmyre to each of the 9 counts of the information and by Chud to counts 6, 7, 8, and 9.

DISPOSITION: 10–16–57. Corporation—$100 fine. Willingmyre—$500 fine and imprisonment for 3 months on count 1; imposition of sentence suspended on counts 2 through 9 and probation for 3 years. Chud—$200 fine on count 6; imposition of sentence suspended on counts 7, 8, and 9, and probation for 2 years.

5354. (F. D. C. No. 40001. S. Nos. 27–563/4 M, 53–004 M, 53–006 M.)

INFORMATION FILED: 4–30–57, S. Dist. Miss., against **Central Wiggins Drug, Inc., t/a Wiggins Drug Store, Pascagoula, Miss., and Alvin W. Caldwell**

(second vice president of the corporation), Robert M. Lauderdale (pharmacist), and William H. Herman (employee).

CHARGE: Between 8-6-56 and 9-5-56, *Bicillin tablets* (counts 1, 2, and 3) were dispensed 3 times and *dextro-amphetamine sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by corporation and Caldwell to the 4 counts of the information and by Herman to counts 1, 2, and 4; nolo contendere by Lauderdale to count 3.

DISPOSITION: 3-7-58. Fine of $50 against corporation, $25 against Caldwell, $115 against Herman, and $10 against Lauderdale.

5355. (F. D. C. No. 39995. S. Nos. 45-062 M, 45-066 M, 45-068 M, 45-070 M, 45-073 M, 45-074 M.)

INFORMATION FILED: 4-16-57, Dist. Md., against **Isadore Horwitz, t/a Smallwood Pharmacy, Baltimore, Md.**

CHARGE: Between 7-10-56 and 8-14-56, *dextro-amphetamine sulfate tablets* were dispensed 4 times and *sulfathiazole tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-14-57. Defendant fined $600, plus costs, and placed on probation for 2 years.

5356. (F. D. C. No. 39979. S. No. 39-231 M.)

INFORMATION FILED: 5-13-57, N. Dist. Ga., against **Charles L. Barfield, t/a Glenhaven Pharmacy, Decatur, Ga.**

CHARGE: On 7-9-56, *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7-18-57. Defendant placed on probation for 2 years.

5357. (F. D. C. No. 38630. S. Nos. 29-245 M, 29-588 M, 30-008/9 M.)

INDICTMENT RETURNED: 9-28-56, S. Dist. N. Y., against **Henry H. Schumann, t/a Schumann's Drug Store, Hunter, N. Y., and Rocco Aversa (pharmacist).**

CHARGE: Between 8-17-55 and 8-24-55, *Selsun* was dispensed twice without a prescription, and *Dexedrine Sulfate tablets* and *Gantrisin tablets* were each dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty by Schumann to dispensing *Dexedrine Sulfate tablets, Gantrisin tablets,* and *Selsun* once each, and by Aversa to dispensing *Selsun* once.

DISPOSITION: 3-11-57. Schumann—jail sentence of 1 year suspended and probation for 2 years; Aversa—probation for 3 months.

5358. (F. D. C. No. 39329. S. Nos. 27-962 M, 27-966 M, 27-968 M, 28-080 M, 28-082 M, 28-086/7 M.)

INFORMATION FILED: 2-13-57, N. Dist. Ga., against **Embry O. Connell and Wilmer Clyde Smith (partners in, and pharmacists for, Biltmore Pharmacy), Atlanta, Ga.**

CHARGE: Between 2–23–56 and 3–5–56, *Metandren Linguets* (counts 1 and 6), *dextro-amphetamine sulfate tablets* (counts 2 and 4), and *Banthine Bromide tablets* (counts 3 and 5) were each dispensed twice and *thyroid tablets* (count 7) were dispensed once without a prescription.

PLEA: Guilty by Connell to counts 1, 2, 5, and 6, and by Smith to counts 3, 4, and 7.

DISPOSITION: 3–12–57. Each defendant fined $500. Jail sentences of 3 months deferred and each defendant placed on probation for 2 years.

5359. (F. D. C. No. 39350. S. Nos. 39–054/9 M.)

INFORMATION FILED: 11–30–56, M. Dist. N. C., against **David Jackson Womble (partner in, and pharmacist for, Womble's Pharmacy), Durham, N. C.**

CHARGE: Between 3–26–56 and 4–12–56, *Neopenzine tablets* and *secobarbital sodium capsules* were each dispensed twice and *sulfadiazine tablets* and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–25–57. Defendant fined $1,000 and placed on probation for 2 years.

5360. (F. D. C. No. 39357. S. Nos. 19–572 M, 19–579 M, 30–696 M, 30–704 M.)

INFORMATION FILED: 12–12–56, W. Dist. Ky., against **Robert L. Saunders, t/a C. Tafel & Son, Louisville, Ky.**

CHARGE: Between 2–3–56 and 2–27–56, *Dexedrine Sulfate tablets* were dispensed twice and *cortisone acetate tablets* and *Gantrisin tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–18–57. $100 fine.

5361. (F. D. C. No. 39390. S. Nos. 28–107 M, 39–087/8 M, 39–093 M.)

INFORMATION FILED: 2–4–57, W. Dist. N. C., against **Henry G. Huber, t/a Sedgefield Drug Co., Charlotte, N. C., and Arthur C. Metcalf (employee).**

CHARGE: Between 5–18–56 and 5–24–56, *Gantrisin tablets* and *Dexedrine Sulfate tablets* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–1–57. Huber—$750 fine, suspended sentence of 2 years, and probation for 3 years; Metcalf—$150 fine, suspended sentence of 1 year, and probation for 2 years.

5362. (F. D. C. No. 39367. S. Nos. 33–067 M, 33–070/1 M, 33–077 M.)

INFORMATION FILED: 1–7–57, Dist. Utah, against **J. Calvin Robinson, t/a Professional Pharmacy, Salt Lake City, Utah, and Albert O. Peterson (pharmacist) and John G. Italasano (pharmacist).**

CHARGE: Between 3–21–56 and 4–17–56, *secobarbital sodium capsules* and *Dexedrine Sulfate capsules* were each dispensed twice upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty—by each defendant to one sale of *secobarbital sodium capsules* and to one sale of *Dexedrine Sulfate capsules.*

DISPOSITION: 5–14–57. All defendants placed on probation for 1 year.

5363. (F. D. C. No. 39984. S. Nos. 39–244/5 M, 39–250 M.)

INFORMATION FILED: 4–29–57, M. Dist. N. C., against **Charles Glenn Lasley, t/a Lasley Drug Store, Draper, N. C., and Thomas Reid Cole (pharmacist).**

CHARGE: Between 8–13–56 and 8–20–56, *secobarbital sodium capsules* were dispensed 3 times upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by Lasley to the 3 counts of the information and by Cole to count 1.

DISPOSITION: 6–5–57. Lasley Drug Store fined $750; Lasley and Cole placed on probation for 2 years.

5364. (F. D. C. No. 40151. S. Nos. 71–870/1 M.)

INFORMATION FILED: 7–12–57, E. Dist. Wis., against **Raymond J. Scherer, t/a R. J. Scherer Drugs, Milwaukee, Wis.**

CHARGE: Between 2–13–57 and 2–14–57, *penicillin G potassium tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8–12–57. $400 fine.

5365. (F. D. C. No. 39987. S. Nos. 39–247 M, 39–251 M, 39–651 M.)

INFORMATION FILED: 4–29–57, W. Dist. N. C., against **Charlotte Drug Co. (a partnership), Charlotte, N. C., and Robert Frank Holland (pharmacist).**

CHARGE: Between 8–18–56 and 9–11–56, *penicillin tablets* were dispensed twice and *Biosulfa tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–5–57. Each defendant fined $500.

5366. (F. D. C. No. 39373. S. Nos. 49–537 M, 49–549 M, 49–568 M, 49–575 M, 49–745/6 M.)

INDICTMENT RETURNED: 6–21–57, Dist. Mass., against **Albert Blank, t/a Eliot Square Pharmacy, Boston (Roxbury), Mass.**

CHARGE: Between 4–9–56 and 5–17–56, *Pentids tablets* and *secobarbital sodium capsules* were each dispensed once upon requests for prescription refills without authorization by the prescriber, and *AM Plus capsules, Premarin tablets, secobarbital sodium capsules,* and *Equanil tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–10–58. $500 fine and sentence of 6 months in jail, plus probation for 2 years.

5367. (F. D. C. No. 39993. S. Nos. 36–468 M, 36–470 M, 36–473 M, 36–475 M, 36–477 M.)

INFORMATION FILED: 4–5–57, N. Dist. Ill., against **David A. M. Levy (pharmacist for Fair Price Drug Corp.), Chicago, Ill.**

CHARGE: Between 5–3–56 and 5–23–56, *penicillin G potassium tablets* were dispensed twice and *Gantrisin tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–29–57. $250 fine, plus costs.

5368. (F. D. C. No. 39398. S. Nos. 56–182/6 M.)

INFORMATION FILED: 2–13–57, N. Dist. Ill., against **Frieden Drug Co. (a corporation), Chicago, Ill., and Joseph Frieden (president and apprentice pharmacist) and John H. Jones (manager and pharmacist).**

CHARGE: Between 6–29–56 and 8–6–56, *Gantrisin tablets* were dispensed 3 times (counts 1, 2, and 4) and *Pentids tablets* (counts 3 and 5) were dispensed twice without a prescription.

PLEA: Guilty—by corporation to all counts, by Frieden to counts 3 and 4, and by Jones to counts 1, 2, and 5.

DISPOSITION: 3–7–57. Corporation—$250 fine, plus costs; Frieden—$200 fine; Jones—$300 fine.

5369. (F. D. C. No. 38611. S. Nos. 12–303/4 M, 18–746/7 M, 29–372 M.)

INFORMATION FILED: 1–22–57, S. Dist. N. Y., against **Weylin Chemists, Inc., New York, N. Y., and Charles Rogers (president and pharmacist), Milton Weinstein (vice president, treasurer, and pharmacist), and Irving Sherman (pharmacist).**

CHARGE: Between 3–17–55 and 6–8–55, *AM Plus capsules* (counts 1 and 4) were dispensed twice and *Oreton M tablets* (count 3) were dispensed once without a prescription, and *Gantrisin tablets* (counts 2 and 5) were dispensed twice upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by corporation to the 5 counts, by Rogers to counts 4 and 5, by Sherman to counts 2 and 3, and by Weinstein to count 1.

DISPOSITION: 2–26–57. Corporation fined $100. Fines of $2 each against Rogers and Sherman and $1 against Weinstein remitted.

5370. (F. D. C. No. 39330. S. Nos. 46–116 M, 46–118 M.)

INFORMATION FILED: 12–7–56, E. Dist. Pa., against **Post Cigar Co., Inc., Upper Darby, Pa., and Louis Balistocky (vice president) and David Zonies (store manager).**

CHARGE: Between 1–11–56 and 1–16–56, *capsules containing a mixture of ergot, apiol, oil pennyroyal, and aloin* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–13–57. Corporation—$400 fine; Balistocky and Zonies—$100 fine each.

5371. (F. D. C. No. 39393. S. Nos. 49–383/4 M, 55–989 M, 55–991/2 M.)

INFORMATION FILED: 2–12–57, N. Dist. Ill., against **Myron S. Steffens (assistant pharmacist for Claridge Pharmacy), Chicago, Ill., and Samuel Solomon (pharmacist).**

CHARGE: Between 2–6–56 and 5–14–56, *Gantrisin tablets* were dispensed 4 times (counts 1, 2, 4, and 5) and *apiol-ergot compound capsules* were dispensed once (count 3) without a prescription.

PLEA: Guilty—by Steffens to counts 1, 2, and 5, and by Solomon to counts 2 and 3.

DISPOSITION: 3–4–57, Solomon fined $100, plus one-half of the costs; 3–12–57, Steffens fined $300, plus one-half of the costs.

5372. (F. D. C. No. 39389. S. Nos. 39-005 M, 39-008/9 M, 39-012 M.)

INFORMATION FILED: 1-24-57, M. Dist. N. C., against **Bowman G. Warren, t/a Warren's Drug Store, Rural Hall, N. C.**

CHARGE: Between 5-31-56 and 6-13-56, *Gantrisin tablets* were dispensed 3 times and *Dexedrine Spansule capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-16-57. $1,000 fine. Defendant placed on probation for 2 years, conditioned that he pay the fine; that he not dispense prescription drugs without keeping records; and that he dispense no more prescription drugs without prescription.

5373. (F. D. C. No. 40150. S. Nos. 49-874 M, 60-833 M, 60-927 M, 60-937 M, 60-939/40 M, 60-982/3 M.)

INFORMATION FILED: 8-14-57, Dist. Mass., against **Cleveland Circle Pharmacy, Inc., Boston, Mass., and Abraham B. Margolis (manager) and Israel Abend (pharmacist).**

CHARGE: Between 1-3-57 and 1-21-57, *Tuinal capsules* (counts 1, 3, and 7) were dispensed 3 times and *Gantrisin tablets* (counts 2 and 5) were dispensed twice upon request for prescription refills without authorization by the prescriber, and *thyroid tablets* (count 4), *Dexedrine Sulfate tablets* (count 6), and *Premarin tablets* (count 8) were each dispensed once without a prescription.

PLEA: Guilty—by corporation to all counts, by Abend to counts 1, 2, and 3, and by Margolis to remaining counts.

DISPOSITION: 4-8-58. Corporation fined $500; Margolis, $300, and sentence of 6 months in jail, which was suspended, and probation for 1 year; and Abend, $200, and probation for 1 year.

5374. (F. D. C. No. 40012. S. Nos. 51-611/2 M, 51-618/9 M, 63-475/6 M.)

INFORMATION FILED: 5-15-57, N. Dist. Tex., against **Alton D. Moss, t/a Moss Rexall Drug, Dumas, Tex.**

CHARGE: Between 7-30-56 and 8-7-56, *Thorazine Hydrochloride tablets* were dispensed twice and *thyroid tablets*, *Neo-Polycin ointment*, *Meticorten tablets*, and *Bacillets troches* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7-23-57. Defendant fined $1,000 and sentenced to 4 months in prison.

5375. (F. D. C. No. 40007. S. Nos. 38-371/3 M, 43-090 M.)

INFORMATION FILED: 7-23-57, E. Dist. Mo., against **Neal Nathanson, t/a Neal Drugs, Webster Groves, Mo.**

CHARGE: Between 6-4-56 and 6-6-56, *diethylstilbestrol tablets* and *Tuinal pulvules* were each dispensed once upon requests for prescription refills without authorization by the prescriber, and *Gantrisin tablets* and *Meticorten tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8-23-57. $300 fine, plus costs.

5376. (F. D. C. No. 40006. S. Nos. 38–370 M, 43–084/5 M, 43–087/8 M, 43–101 M.)

INFORMATION FILED: 7–5–57, E. Dist. Mo., against **Charles R. Davis and Francis A. Mueller (manager and assistant manager, respectively, of Gasen Drug Store No. 3), St. Louis, Mo.**

CHARGE: Between 6–1–56 and 7–7–56, *diethylstilbestrol Enseals* (timed disintegrating tablets) and *Tuinal pulvules* were each dispensed twice and *Gantrisin tablets* and *Serpasil tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Davis to 3 counts and by Mueller to the 3 remaining counts.

DISPOSITION: 9–4–57. Each defendant fined $600, plus costs, given a jail sentence of 6 months, which was suspended, and placed on probation for 1 year.

5377. (F. D. C. No. 40142. S. Nos. 52–589 M, 52–591 M, 52–593 M, 62–761/3 M.)

INFORMATION FILED: 7–1–57, E. Dist. N. Y., against **Hy's Pharmacy (a partnership), Brooklyn, N. Y., and Hyman Weiss (partner).**

CHARGE: Between 9–27–56 and 10–24–56, *Gantrisin tablets* and *Tuinal capsules* were each dispensed twice and *Chloromycetin capsules* and *Metandren Linguets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10–31–57. $600 fine against each defendant.

5378. (F. D. C. No. 39396. S. Nos. 39–952 M, 39–954 M, 39–956/7 M.)

INFORMATION FILED: 2–4–57, N. Dist. Ill., against **Abraham A. Schwartz, t/a Center Cut Rate Drugs, Chicago, Ill.**

CHARGE: Between 5–10–56 and 6–25–56, *Aureomycin capsules, Achromycin capsules, Seconal Sodium tablets,* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–20–57. The court imposed a fine of $400 of which $200 was suspended, and ordered the defendant to serve 1 hour in the custody of the United States marshal.

5379. (F. D. C. No. 39999. S. Nos. 34–246 M, 34–248 M.)

INFORMATION FILED: 7–9–57, W. Dist. Okla., against **Charles Vance Dodge, t/a Dodge Drug Store, Ponca City, Okla.**

CHARGE: Between 8–23–56 and 9–21–56, *Aureomycin capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 9–6–57. $20 fine.

5380. (F. D. C. No. 40146. S. Nos. 47–076/9 M, 47–085/6 M, 59–179 M.)

INFORMATION FILED: 7–18–57, E. Dist. Pa., against **Hill Pharmacy (a partnership) and Joseph J. Kaback (partner).**

CHARGE: Between 1–1–57 and 1–28–57, *Tuinal capsules* were dispensed three times and *Achromycin capsules* and *secobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–7–57. Fine of $1,500 and probation for 2 years against defendants jointly.

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